STATE OF CALIFORNIA--HEALTH AND WELFARE AGENCY

PAM PATRICIDES

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DEPARTMENT OF HEALTH SERVICES

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MMCD Policy Letter 98-06

TO:

[X] County Organized Health System

[X] Geographic Managed Care Plans

[X] Prepaid Health Plans

[X] Primary Care Case Management

SUBJECT: NEWBORN AND PRENATAL GENETIC SCREENING SERVICES

BACKGROUND

State law requires that all women seen for prenatal care prior to 20 weeks gestation be offered prenatal blood testing in the Department of Health Services' (DHS) expanded alpha-fetoprotein (AFP) program and that all newborns be screened for certain treatable heritable disorders. DHS' Genetic Disease Branch administers the newborn and prenatal screening programs. Initial newborn and prenatal genetic screening laboratory services are provided through a network of state-approved laboratories supported by area genetics centers.

GOAL

To assure that pregnant women and newborns are provided timely and effective genetic disease prevention, early detection and diagnosis, treatment and education and counselling services.

POLICY

I. Newborn Screening

State law [California Code of Regulations (CCR), Title 22, Sections 51348.1, 51529 (d) and CCR, Title 17, Sections 6500 through 6510] requires all newborns to be screened for a series of treatable heritable disorders (PKU, galactosemia, hypothyroidism, sickle cell disease, and related hemoglobinopathies) prior to discharge from the hospital of birth. Plans are responsible for implementing procedures to ensure that perinatal care providers appropriately obtain the required blood specimens from all newborns, using DHS approved specimen collection forms. Specimens must

be submitted to DHS approved laboratories only (see Attachment 1). Follow-up tests requested by the Newborn Screening (NBS) program are also done by these DHS approved laboratories. The fee currently charged by DHS for initial and necessary follow-up tests is $42, as set by regulation (CCR, Title 17, Section 6508) and is charged to the hospital of birth. For out of hospital births, the attending physician or midwife is billed. Plans are capitated for these charges and are responsible for reimbursement arrangements with affected network perinatal service providers, since these providers are no longer able to separately bill Medi-Cal fee-for-service (FFS) for reimbursement.

The area genetics center notifies the infant's primary care physician (PCP) of record of an initial presumptive positive test result and of the results of follow-up tests. Newborns with confirmed positive tests are California Children Services (CCS) eligible and the plan should assure that these infants are referred to the appropriate county CCS office. The plan remains responsible for the provision of all non-CCS related medical services for the member and for coordination of care with the CCS program.

II. Prenatal Screening

State law requires that all women seen for prenatal care prior to 20 weeks gestation be offered screening blood tests for the detection of individuals at increased risk for carrying a fetus with certain heritable and congenital disorders. The prenatal care provider should offer screening tests to the pregnant member at the first prenatal visit. Testing occurs through DHS' Expanded AFP Program (CCR, Title 17, Sections 6521 through 6532), which currently offers triple marker screening. Triple marker screening tests the woman's serum for AFP, unconjugated estriol (UE) and human chorionic gonadotrophin (HCG). The risk for open neural tube defects, abdominal wall defects, trisomy 21 (Down Syndrome) and trisomy 18 are estimated based on the woman's age and serum values. Only laboratories designated by DHS may be used for this test. A member's participation in the Expanded AFP Program is voluntary. The members consent or refusal to participate must be documented.

A regional Expanded AFP coordinator will call the prenatal care provider if the test result is screen positive. For women with positive tests who are at high risk of a birth defect, the Expanded AFP Program provides follow-up diagnostic services. These services are offered through State-approved Prenatal Diagnosis Centers (PDC) (see Attachment 2) and include genetic counseling, amniocentesis, and amniotic fluid analysis including karyotype.

Triple marker testing and necessary follow-up services are "carved-out" of plan's contracts and must be billed FFS. Plans must assure that their perinatal providers

understand how to participate in and access this system for members, in accordance with regulations. Prenatal care providers should be directed to enter the patients' Medi-Cal number on the test request form provided by the State in the billing information space. The Expanded AFP Program will then bill Medi-Cal directly. Except for the services provided under the Expanded AFP Program, plans remain responsible for the provision of all necessary medical services for the pregnant member, including any amniocentesis believed by plan providers to be medically necessary, regardless of the results of the Expanded AFP tests. Some women over age 35 may decide not to use the Expanded AFP Program and opt instead to request a diagnostic amniocentesis. The plan is responsible for authorizing and providing this procedure.

III. Member Education

The plan must implement procedures which assure that pregnant members are informed that newborns must be screened for certain treatable hereditary disorders. State law (CCR, Title 17, Section 6504) requires that all perinatal care providers provide pregnant women with a copy of DHS' document titled "Important Information for Parents," which contains information concerning newborn screening.

The Expanded AFP Program has developed patient education booklets for women under 35 years of age at term and for women 35 years of age and older at term. These booklets are to be given at the first prenatal visit to all pregnant women who are seen before the 20th gestational week in order to help them choose whether or not to voluntarily participate in the Expanded AFP Program; to select a diagnostic test or to forego both options. A member must be informed that her participation in the program is voluntary and her decision to participate or not to participate must be documented. Plan perinatal providers must coordinate their services with the follow-up services provided by the Expanded AFP Program.

Translated materials, in the appropriate threshold and concentration standard languages, should be available to plan members. If the mnterials are unavailable in the member's language, the information should be read to the member.

IV. Provider Training

Plans must ensure that network providers delivering perinatal and/or pediatric services and relevant support staff are knowledgeable regarding the requirements of the Newborn Screening Program and the Expanded AFP Program. Network providers are required to follow all State laws governing the provision of newborn screening and expanded AFP services, including complying with all mandated genetic disorder

reporting requirements. A copy of the most current CCR sections governing these services, including reporting requirements, is enclosed with this policy letter (see Attachment 3).

DISCUSSION

DHS' Genetic Disease Branch administers several other programs, in addition to the Newborn Screening Program and Expanded AFP Programs. These include, but are not limited to, the Tay-Sachs Disease Prevention Program and the Maternal PKU Program. In addition, the State Genetic Disease Laboratory provides, at no charge, phenylalanine blood tests to monitor the medically required low phenylalanine diet for treatment of PKU. Plans are encouraged to educate network providers regarding the services and materials available through DHS' Genetic Disease Branch.

If there are any questions regarding this policy letter, please contact your contract manager.

Ann-Louise Kuhns, Chief
Medi-Cal Managed Care Division

Enclosures

Attachment 1

Newborn Screening Panel

All newborns must be screened for preventable forms of mental retardation under regulations issued by the Department of Health Services (17, CCR, 6500). The Department of Health Services, Genetic Disease Branch, has contracted with six clinical laboratories to perform the required tests on Medi-Cal recipients. The designated screening panel consists of the following laboratory tests:

1. Radioimmune assay for T4
2. Radioimmune assay for TSH
3. Qualitative fluoromsrric blood phenylalanine
4. Galactose - 1- uridyltransferase
5. Microbial inhibition assay for blood galactose

The laboratories listed below perform these tests and are reimbursed under contract by the Genetic Disease Branch.

The designated testing laboratories are:

Western Clinical Laboratory
408 Sunrise Avenue
Roseville, CA 95678

American Clinical Laboratory
10477 - C Roselle Street
San Diego, CA 92121

Allied Medical Laboratory
20392 Town Center Lane
Cupertino, CA 95014

Reference Laboratory
1011 Rancho Conejo Blvd.
Newbury Park, CA 91320

Fresno Community Hospital
and Medical Center
Fresno and "R" Streets
Fresno, CA 93715

Memorial Hosp. of Long Beach
2801 Atlantic Avenue
Long Beach, CA 90806

Attachment 2

Prenatal Diagnosis Centers and Satellite Locations

State-approved for Expanded AFP Follow-up

Southern California

Alfigen/The Genetics Institute
Pasadena
(818) 666-3300
Santa Barbara, San Luis Obispo, Palm Spring Bakersfield, Pomona, Los Angeles, Tarzana, Ventura, Torrance, West Covina, Whittier, Lo Beach, Inglewood, Monterey Park, Garden Grove, Santa Maria, San Diego, Irvine

Cedars-Sinai Medical Center
Los Angeles
(310) 855-2214
Van Nuys

Childrens Hospital of Los Angeles
Los Angeles
(213) 669-2478

Genesis Laboratories
Redlands
(909) 335-5610

Genetics Center
Orange
(714) 667-0878
Irvine Mission Viejo Bakersfield

Genzyme Genetics
Long Beach
(800) 745-4363 x 7011
Laguna Hills, Newport Beach Torrance, Anaheim, Thousand Oaks Ventura, Fountain Valley, Lancaster Tarzana, Inglewood, Palm Springs

Kaiser Permanente
Panorama City
(626) 564-3322
Bellflower, Fontana, Harbor City, Los Angeles, Anaheim, Riverside, West LA, Woodland Hills, Baldwin Park, San Diego

King Drew Prenatal Diagnosis Center
Los Angeles
(310) 668-4620
Lynwood

LA County/USC Medical Center
Los Angeles
(213) 226-3256

Loma Linda University Medical Center
Loma Linda
(909) 478-6505
Riverside, La Mirada, Fountain Valley, Victorville

Prenatal Diagnosis Center of Southern California
Beverly Hills
(310) 652-5884

Prenatal Diagnostic & Perinatal Center
San Bernardino
(909) 881-4503
Apple Valley, Indio, Riverside, Corona, Wildomar, Montclair, Pasadena, West Covina Burbank, Oceanside, Loma Linda

Sharp/Children's Prenatal Diagnosis Center
San Diego
(619) 541-6860

U.C. Irvine
Orange
(714) 456-5780
Santa Ana

U.C.L.A. Medical Center
Los Angeles
(310) 825-0300
Northridge, Sylmar, Santa Barbara Santa Moncia

U.C. San Diego
La Jolla
(619) 597-2600
El Centro

Northern California

Alfigen/The Genetics Institute
(408) 559-2258
San Jose, Monterey, Salinas, Walnut Creek

Alta Bates Perinatal Center
Oakland
(510) 204-5359

California Pacific Medical Center
San Francisco
(415) 750-6400
Greenbrae, Santa Rosa

East Bay Perinatal/Children's Hospitial
Oakland
(510 653-3335
Walnut Creek San Ramon

Genzyme Genetics
(408) 885-7925
San Jose

Kaiser Permanente
Oakland
(510) 596-6298
Sacramento, San Francisco, San Rafael, San Jose, Hayward

Prenatal Diagnosis of Northern California
Sacramento
(916) 736-6868
Stockton Fairfield, Modesto

Prenatal Diagnostics, Inc.
Mountain View
(415) 964-1505
Los Gatos, Palo Alto, San Mateo, Fremont, Salinas, San Jose

Stanford University
Stdniorcl
(415) 723-5198
Mountain View

Sutter Prenatal Diagnosis Center
Sacramento
1916, 733-1900

U.C. Davis
Sacramento
(916) 734-6124
Carmichael, Davis, Redding

U.C. San Francisco
San Francisco
(415 476-4080
Corte Madera Santa Rosa

Valley Children's Hospital
Fresno
(209) 243-6633

Appendix

A

Expanded AFP Coordinator Offices

Northern California

San Francisco
(415) 476-1692
Fax (415) 502-0867

Sacramento
(916) 734-6575
Fax (9 16) 734-6025

Oakland
(510) 428-3769
Fax (510) 450-5874

Palo Alto
(415) 723-6894
Fax (415) 725-2878

Fresno
(209) 225-5108
Fax (209) 225-8561

Kaiser Permanente
(510) 596-6190
Fax (510) 596-6800

Southern California

Los Angeles
(310) 855-2154
Fax (2 13) 653-9655

Los Angeles
(213) 221-5606
Fax (2 13) 224-0340

Los Angeles (Torrance)
(310) 212-0816
Fax (310) 782-7704

Los Angeles, Ventura, Santa Barbara
(310) 206-8211
Fax (310) 794-1290

Orange
(714) 456-5994
Fax (714) 456-7817

Riverside/San Bernardino
(909) 890-3123
Fax (909) 890-3 120

San Diego
(619) 822-1280
Fax (619) 822-1284

Kaiser Permanente
(626) 5643322
Fax (626) 564-3311

An Expanded AFP coordinator office phone number is listed on all result mailers.

Call (5 10) 540-2 534 for questions.

Attachment 3

History

mendment of subsection (b)(3) filed 4–15–80 as an emergency; effective upon filing (Register 80, No. 16). A Certificate of Compliance must be transmitted lo OAH within 120 days or emergency language will be repealed on R-14-80.

2. Certificate of Compliance transmitted to OAL 7-29-80 and filed 8–20–80 (Register 80. No. 34).

3. Amendment of subsection (a), new subsections (a)(1)–(3), and amendment of subsection (b)(3) and NOTE filed 3-29-96: operative 4–28–96 (Register 96, No. 13).

4. Editorial correction of subsection (b)(3) (Register 97, No. 12).

5 Amendment of subsection (b)(3) and NOTE filed E-22-97 as an emergency; operative 5-22-97 (Register 97, No. 21). A Certificate of Compliance must be transmitted to OAL by 9–19–97 or emergency language will be repealed by operation of law on the following day.

Subchapter 8.1. Immunization Against Measles (Rubeola)

History

1. Repealer filed 3–22–78 as an emergency, effective upon filing (Register 78, No. 12). For prior history, see Registers 67, No. 43; 67. No. 48; and 72. No. 1 I.

Subchapter 8.2. Immunization Against Diphtheria, Tetanus, and Pertussis

History

I. Repealer filed 3-22-78 as an emergency. effective upon filing (Register 78. No. 12). For prior history, see Register 72, No. Il.

Subchapter 9. Heritable Diseases

Article 1. Testing for Preventable Heritable Disorders

§ 6500. Definitions.

(a) Preventable Heritable or Congenital Disorders. "Preventable heritable or congenital disorders" means any disorder or abnormality present at birtb which is detectable by testing a newborn and for which effective means of prevention or amelioration exist.

(b) Newborn. "Newborn" means an infant 30 days of age and under.

(c) Birth Attendant. "Birth attendant" means any person licensed or certified by the State to provide maternity care and to deliver pregnant women or to practice medicine.

(d) Perinatal Licensed Health Facility. "Perinatal licensed health facility" means any health facility licensed by the State and approved to provide perinatal, delivery, newborn intensive care, newborn nursery or pediatric services.

(e) Days of Age. "Days of age" means the measurement of the age of a newborn in 24–hour periods so that a newborn is one day of age 24 hours following the hour of birth.

(f) Discharge. "Discharge" means release of the newborn from care and custody of the perinatal licensed health facility to tbe parents or into tbe community.

(g) Transfer. "Transfer" means release of tbe newborn from care and custody of one perinatal licensed health facility to care and custody of another perinatal licensed health facility. or admission to another perinatal licensed health facility of a newborn in an out-of-state facility.

(h) Newborn's Physician. "Newborn's physician" means the physician responsible for the care of the newborn after discharge from the hos-

(i) Initial Specimen. "Initial specimen" means the first specimen collected subsequent to birth. pursuant to these regulations.

(j) Initial Test. "Initial test" means tbe fist valid newborn screening test or combination of tests of a newborn for each disorder covered by these regulations.

(k) Initial Presumptive Positive Test. "Initial presumptive positive test" means a newborn's blood spximen which is defined as positive for reporting purposes.

(l) Inadequate Specimen. "Inadequate specimen" means a newborn's blood specimen which is not suitable in quality or quantity to perform newborn screening for one or more of the disorders covered by these regulations.

(m) Repeat Specimen. "Repeat specimen" means a specimen collected from a newborn following the newborn screening laboratory's report that a previously collected specimen was either madequate or that test results were inconclusive

(n) Repeat Test. "Repeat test" means a test required by these regulations to be repeated for a newborn because the previous specimen or test results were inadequate or test results were not complete.

(o) Recall Specimen. "Recall specimen" means a specimen collected from a newborn because the initial test orcombination of tests was presumptive positive for any of the disorders covered by these regulations.

(p) Recall Test. "Recall test" means a test ordered collected from a newborn because the initial test orcombination of tests was presumptive positive for any of the disorders coveted by these regulations.

(q) Newborn Screening Laboratory. "Newborn screening laboratory" means a laboratory operated by the Department or a laboratory contracting with the Department to conduct tests required by this article.

(r) Area Genetic Center. "Area genetic center" means an institution, corporation, hospital or university medical center having specialized expertise designated by the Department to serve a specific geographic area of the State which has contracted with the Department toprovide follow–up. referral and diagnosis of a preventable heritable or congenital disorder as defied in this Article.

(s) Sickle Cell Education and Counseling Program. "Sickle cell education and counseling program" means an educational and counseling program in which the disease orientation is. in whole or in major part. sickle cell disease.

(t) Sickle Cell Counselor. "Sickle cell counselor" means a person who provides face to face information on the medical, social, and genetic consequences of sickle cell disease and trait and who has successfully completed an approved sickle cell counselor training program and is certified as such by the Department of Health Services. Physicians and individuals with a master's degree in genetic counseling who are board eligible or board certified by the American Board of Medical Genetics are not required to complete such a training program.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 309, 325, 326 and 327. Health and Safety Code.

History

1. New subchapter 9 (section 6500) filed 12-I-65; designated effective 1–1–66 (Register 65, No. 23).

2. Amendment filed 10–5–66; effective thirtieth day thereafter (Register 66, No. 34)

3. Repealer filed 4-l 1–80; designated effective 9-I-80 (Register 80, No. 15).

4. Renumbering and amendment of former section 6500.5 to section 6500 filed 11-21-86; effective thirtieth day thereafter (Register 86, No. 47).

5. Amendment of subsection (r) and new subsections (s) and (t) filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90, No. 4).

6. Amendment of subsection(t) filed by the Department of Health Services with the Secretary of State on 5–30–90 as an emergency; operative 5–30–90. Submined to OAL fox printing only pursuant to Health and Safety Code section 309(g)(Register 90, No 30).

7. Editorial correction of printing error in subsection (r) restoring HISTORY 5. and renumbering previous HISTORY 5. to 6. (Register 91, No. 32).

§ 6500.1. Effective Date of Repeal and Implementation.

NOTE: Authority cited: Section 208. Health and Safety Code: Reference: Sections 51 and 309, Health and Safety Code.

History

New section filed 4–11–80; designated effective 9–1–80 (Register 80, No. 15).

2 Amendment filed R-29-80 as an emergency: effective upon filing (Register 80. No. 35) A certificate of compliance must be filed within 120 days or emergency language will be repealed on 12–28–80.

5. Certificate of Compliance transmitted to OAL 12-15-80 and filed 1-21-81 (Register 81, No. 3).
4. Repealer filed 11-21-86; effective thirtieth day thereafter (Register 86, No 47).

§ 6500.5. Definitions.

History

1. New section filed 4-I l-80: designated effective 9-1-W (Register 80, No. 15)
2. Renumbering and amendment of former Section 6500.5 to Section 6500 filed I I-21-86; effective thirtieth day thereafter (Register X6, No. 47).

§ 6501. Scope of Newborn Testing.

(a) Each newborn born in California shall be tested for hereditary hemoglobinopathies, phenylketonuria, hypothyroidism and galactosemia in accordance with procedures in this Article

(b) The provisions of Section 6501 (a) shall not apply if a patent or legaily appointed guardian objects to a test on the ground that it conflicts with his or her religious beliefs or practices. If the parent or legal guardian refuses to allow the collection of a blood specimen, such refusal shall be made in writing and signed by a patent or legally appointed guardian and included in tie newborn's medical or hospital record.

(c) The provisiuts of Section 6501(a) shall not apply if the newborn has a condition almost certainly to be fatal in the first thirty (30) days of life which shall be documented in the medical record.

NOTE: Authority cited: Section 309, t lealth and Safety Code. Reference: Sections 151, 154, 155, 309, 325, 326 and 327. Health and Safety Code.

History

1. New section filed 4-1 I-80: designated effective 9-I-80 (Register 80, No. 15).
2. Amendment filed I I-21 -86; effective thirtieth day thereafter (Register 86, No. 47).
3. Amendment of subsections (a) and (c) filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code Section 309(g) (Register 90, No. 4).

§ 6502. Laboratory Tests.

NOTE: Authority cited: Sections IS l and 208. Health and Safety Code. Reference: Section 309. Health and Safety Code.

History

1 New section filed 4-1 l-80; designated effective 9-I-80 (Register 80. No. I).
2. Repealer filed I I-21-86: effective thirtieth day thereafter (Register 86. No. 47).

§ 6502-f. Confidentiallty.

(a) All information records of interview, written reports, statements. notes. memoranda, or other data pt .ured by an individual, group or research team in the course of any testing under this article shall be confidential and shall be used solely for the purposes of medical intervention. counseling. or specific research project approved by the Department.

(b) Except as provided bylaw, such information shall not be exhibited nordisclosed in any way, in whole or in part, by any individual. group, or research team except with the written consent of the person or his/her legally authorized representative unless such data can be made available in a manner which preserves anonymity of the persons tested.

NOTE- Authority cited: Section 309. Health and Safety Code. Reference: Sections 151 and 309, Health and Safety Code.

History

1. New section filed by the Department of Health Seniors with the Secretary of State on 5-30-90 as an emergency; operative S-30-90. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90. No. 30).

§ 6503. Newborn Screening Laboratories.

(a) The Department shall designate laboratories and tests to be used for Department required newborn tests. Such laboratories shall be *either lab*oratories operated by the Department for quality control confirmatory and emergency testing or contractor laboratories licensed as clinical laboratories under the Business and Professions Code.

(b) Perinatal licensed health facilities and birth attendants shall submit required specimens to the newborn screening laboratory designated by the Department.

(c) Contract newborn screening laboratories shall be limited to laboratories that shall have submitted a bid acceptable to the Department on a competitive contract to provide laboratory services in sufficient volume to cover all of the newborns born in a geographical area. as defined by the Department. plus an appropriate emergency capacity. The Department will define not more than six areas and may combine areas if necessary to reduce costs or assure statewide coverage.

(d) Notwithstanding (c) above a comprehensive prepaid group practice direct health cam service plan with 20,000 or more births in the last completed calendar year for which complete statistics are available may have a laboratory serving a comprehensive prepaid group practice health care service plan designated a newborn screening laboratory under terms of a written agreement as defined in Section 6508(b) or may provide services in conformity with the terms of a mutually acceptable contract for services.

(e) Newborn screening laboratories shall participate in a proficiency testing program conducted by the Department's laboratory and shall maintain levels of performance acceptable to the Department.

(f) Newborn screening laboratories contracting with the Department shall be subject to on-site inspections and review of laboratory performance of tests and laboratory records.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Sections 151 and 309. Health and Safety Code.

History

1. New section filed 4-11-80; designated effective 9-1-80 (Register 80, No. 15)
2. Amendment filed 8-29-80 as an emergency; effective upon filing (Register 80, No. 35). A certificate of compliance must be filed within 120 days or emergency language will be repealed 12-28-80.
3. Certificate of Compliance transmitted to OAL 12-I 5-80 and filed I- 12-8 I (Register 81, No. 3).
4. Amendment filed I 1-21-86; effective thirtieth day thereafter (Register 86. No. 47).
5. Amendment of subsections (d) and (e) filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code Section 309(g) (Register 90, No. 4).

§ 6504. Use of Newborn Screening Forms.

(a) All birth attendants engaged in providing perinatal care shall provide pregnant women. prior to the estimated date of delivery, with a copy of the informational material, titled "Important Information for Parents," provided by the Department.

(b) Perinatal licensed health facilities shall provide each pregnant woman admitted for delivery with a copy of the informational material provided by the Department, titled "Important Information for Parents." prior to collection of the blood specimen if such information has not been provided pursuant to subsection (a) above. If a woman is unable to read such material, it shall be translated or read to her in a language she understands.

(c) Department approved specimen collection forms shall not be copied. printed, reproduced. acquired, purchased or distributed other than as provided for in these regulations.

(d) Such Department approved specimen collection forms shall be fully and accurately completed by birth attendants. perinatal licensed health facilities and laboratories and a copy shall be filed in each newborn's medical record.

(e) Perinatal licensed health facilities shall *maintain* such records as are necessary to assure compliance with these regulations and provide the Department with such data as may be periodically required including. hut not limited to. information on all newborns discharged or transferred from the facility without collection of a blood specimen. All such information and records shall be confidential but shall be open to examination by the Department personnel or its designated agents for any purpose directly connected with the administration of the new born screening program.

(f) Birth attendants or physicians shall provide to parent(s) or legally appointed guardian(s) who object to the tests on the basis it is in conflict with their religious beliefs or practices, a refusal form approved by the Department and shall obtain the appropriate signature(s) upon the form. If the parent(s) or legally appointed guardian(s) is unable to read such material, it shall be translated or read to such person(s) in a language understood by such persons.

NOTE Authority cited: Section 309, Health and Safety Code. Reference: Sections 151 and 309. Health and safety Code.

HISTORY

1. New section filed 4 I I -80; designated effective 9 I-80 (Register RO. No. 15).
2. Amendment of subsection (f) filed 8-29-80 as an emergency (Register 80. No. 35). A certificate of compliance must be filed within 120 days or emergency language will be repealed on 12 28 80.
3. Certificate of Compliance transmitted to OAL 12 15-80 and filed I 12-81 (Register 81. No. 3).
4. Repealer and new section fikd 1 I 21-86; effective thirtieth day thereafter (Register 86. No. 47).

§6505. Collection of Specimens.

(a) Birth attendants. laboratories and hospitals shall collect specimens using the technique for blood collection distributed by the Department.

(b) Physicians or birth attendants who arc caring for newborns born in perinatal licensed health facilities shall have blood specimens collected using Department approved specimen collection forms in accordance with criteria distributed by the Department including the following:

(1) A specimen must be collected from any untested infant prior IO blood transfusion.

(2) For newborns discharged before six days of age. a blood specimen shall be obtained as close IO the time of discharge from the perinatal licensed health facility as is practical regardless of age or feeding history. unless the newborn is transferred for continuing care to another perinatal licensed health facility on or before the sixth day of age. Perinatal licensed health facilities which discharge infants before 24 hours of age may request a waiver from this requirement *documenting* how such *new*borns will be tested on or before 6 days of age. Such alternative testing schedules must be approved in writing by the Department.

(3) For newhoms remaining in perinatal licensed health facilities beyond five days of age. a blood specimen shall be obtained from the newborn on the sixth day of age regardless of feeding history.

(4) For newborns received by transfer on or before six days of age. the receiving hospital shall obtain a blood specimen as close IO discharge as possible. and if not discharged by the sixth day. a blood specimen shall be obtained on the sixth day of life.

(c) *Fornewborns* not born in a perinatal licensed health facility but admitted to a perinatal licensed health facility within the first six days of age. a specimen shall be obtained as close IO discharge as possible. and if not discharged by the sixth day of life. a blood specimen shall be ohtaincd on the sixth day of life unless the newborn's physician has evidence that the specimen was previously obtained and records the result of the test in the newborn's medical record.

(d) For newboms not born in a perinatal licensed health facility but admitted to a perinatal licensed health facility after six days of age but within the first 30 days of age. a blood specimen shall be obtained within 48 hours after admission unless the newborn's physician has evidence that the specimen was previously obtained and records the results of the test in the newborn's medical record.

(e) Physicians attending sick newborns who exhibit symptoms suggestive of galactosemia. hypothyroidism or phenylketonuria (PKU). in addition to immediate diagnostic tests from local laboratory sources. shall have a blood specimen collected from the newborn and submitted IO a newborn screening laboratory using forms purchased from the Department.

(f) Physicians attending critically ill newborns who require special care may postpone collection of a blood *specimen* until the newborn's emergency life threatening condition is stabilized.

(g) Birth attendants or physicians attending newborns not born in a perinatal licensed health facility and not subsequently admitted to a licensed health facility during the fist six days of age. shall have a blood specimen collected from the newborn between the second and sixth days of age and submitted to a newborn screening laboratory using forms obtained from the Department.

(h) If a newborn is born outside of a perinatal licensed health facility and the birth is not attended by a birth attendant and the newborn is not subsequently admitted to a perinatal licensed health facility within the first ten days of age. the person required to register the birth shall arrange for a blood specimen IO be collected and submitted to a newborn screening laboratory between the second and tenth day of age.

(i) Initial specimens shall be collected using a Department -approved form and shall beplacedinthc United States mail or other approved channel of transmittal lo the assigned Department&approved laboratory as soon as possible. but not later than 12 hours after they are obtained.

(j) The blood specimen and information obtained during the testing process becomes the property of the State and may be used for program evaluation or research by the Department or Department approved scientific researchers without identifying the person or persons from whom these results were obtained. unless the person or his/her legally authorized representative specifically prohibits such use in writing.

Non:: Authority cited: Section 309. Health and Safety Code. Reference: Sections IS I and 309. Health and Safety Code.

HISTORY

1. New section filed 4 I I 80; designated effective 9 180 (Register 80. No. I 5) For history of former section. see Registers 78. No. 34 and 74. No. 18.
2. Amendment of subsection (it filed 8 29 HO as an emergency; effective upon filing (Register 80. No. 35). A certificate of compliance must be filed within 1 20 days or emergency language will be repeated on 12 28-80.
3. Certificate of Compliance transmitted to OAL 12-IS 80 and filed I I2 81 (Register RI. No. 3).
4. Repealer and new section filed I I -21-86; effective thirtieth day thereafter (Register 86. No. 47).
5. Amendment of subsections (b). (c). (f) and (i). and new subsection (j) filed hy UK Department of Health Services with the Secretary of State on I2 22 89 as an emergency; operative 12-22-89. Submitted to OAL for printing only pursuant IO Health and Safety Code Section 309(g) (Register 90. Nn. 4).

36506. Reporting and Follow-Up of Tests.

(a) Perinatal licensed health facilities shall *review* each newborn's medical record within 14 days from the date of discharge IO determine that the results of required tests are filed in the newborn's medical record. or that a parent's or legal guardian's signed refusal has been filed in the newborn's medical record.

(b) Whenever a perinatal licensed health facility determines that a discharged newborn has not received the mandated tests, the facility shall contact the newborn's physician by telephone IO inform him/her that a specimen must be obtained and immediately send written notification to the newborn's physician and the Department. If the newborn's physician cannot be contacted or will not obtain a specimen. the perinatal licensed health facility shall notify the Department-approved area genetic crntcr by telephone and shall send written notification within five days to the area genetic center and the Department.

(c) Whenever a perinatal licensed health facility determines that a specimen has been obtained. but therearenoresultsavailablc in the newborn's medical record the facility shall send writlen notification within five days to the Department.

(d) When the newborn's physician is notified by tclephonc by the perinatal licensed health facilitythatanewbom was discharged from the perinatal licensed health facility before a specimen was taken. the newborn 's physician shall make every reasonable effort to have a specimen obtained within five days of notification. If the newborn's physician cannot obtain the specimen. the area genetic center shall he notified by the newborn's physician by telephone. Such telephone notification shall be noted in the newborn's physician's records. specifying the date of notification. the person notified and the information provided.

(e) When a newborn's physician is notified by the laboratory by telephone that a specimen is inadequate. the physician so notified shall make every reasonable effort to have an adequate specimen obtained within five days of notification. if the newborn's physician so notified. cannot obtain the repeat specimen. the physician shall notify the area genetic center as soon as possible by telephone. Such telephone notification shall be noted in thencwbom's physician'srecords specifying the date of notification, the person notified and the information provided.

(f) When the newborn's physician is notified by telephone by the Department- approved area genetic center of an initial presumptive positive test result the newborn's physician shall obtain an adequate recall blood specimen from the newborn and submit it to the designated laboratory

within 48 hours. If the recall blood specimen cannot be obtained within 48 hours. the newborn's physician shall notify the area genetic center by telephone. Such telephone notification shall be noted in the newborn's physician's records. specifying the dale of notification. the person notified and the information provided.

(g) Repeat and recall specimens required by these regulations shall be collected on Department approved forms. placed in appropriate containers, and shall be placed in the United States mail or other approved channel of transmittal to the assigned. Department--approved laboratory as soon as possible. but not later than 12 hours after they have been obtained.

(h) All physicians making an initial diagnosis of a preventable heritable disorder for which testing is required under this Article shall report such diagnosis and the information necessary for follow-up and investigation to the Department.

(i) Willful or repeated failure to comply with these regulations shall he referred by any person having knowledge of non compliance io the appropriate licensing authority. Failure to report may constitute grounds for disciplinary action including revocation of license.

NOTE: Authority cited: Section 309. Health and Safety Code. Reference: Sections IS I and 309. Health and Safety Code.

HISTORY

1. New Section filed 4-11-80; designated effective 9-1-80 (Register 80, No. 15).
2. Repealer and new section fikd I 121-86; effective thirtieth day thereafter (Regiskr 86. No. 47).

§ 6507. Local Agencies Responsibilities.

NOTE: Authority cited: Section 309, Health and Safety Code. Refermce: Sections 151 and 309, Health and Safety Code.

HISTORY

1. New section filed 4-11-80; designated effective 9-1 80 (Register 80, No. 15).
2. Repeakr ad new section filed I 1-21 46: effective thirtieth day thereafter (Register 86, No. 47).
3. Renumbering of Section 6507 to Section 6507. I filed by the Department of Health Services with the Secretary of Stale on 12-22-89 as an emergency. operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code Section 309(g) (Register 90, No. 4).

§ 6507.1. Local Agencies Responsibilities.

(a) the county registrar shall provide a copy of the informational material prepared and provided by the Department to each person registering the birth of a newborn that occurred outside of a perinatal licensed health facility when the said newborn was not admitted IO a perinatal licensed health facility within the first 30 days of age. The local health officer and the Department shall be notified of each such registration by the county registrar.

(b) Each local health department in the county where a newborn resides shall be responsible for making every reasonable effort to obtain specimens when requested by the Department-approved area genetic center or the Department. If aftereveryreasonable effort a specimen cannot be obtained. the local health department may. after 30 days. with approval from the Department, terminate efforts.

NOTE: Authoritycited: Section 309. Health and Safety Code. Reference: Sections 151 and 309, Health and Safety Code.

HISTORY

1. Renumbering of former Section 6507 to Section 6507.1 filed by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency: operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code Section 309(g) (Register 90, No. 4). For prior history. see Register 86, No. 47.

§ 6507.2. Sickle Cell Education and Counseling Programs.

(a) Each sickle cell education andcounseling program shall apply for and obtain written approval from the Department of Health Services. Such approval shall be contingent upon compliance with all sections of these regulations.

(b) Each sickle cell education and counseling program shall:

(1) Provide counseling services to the clients.

(2) Employ State approved sickle cell counselors to perform all of the counseling following. or relating to. any abnormal hemoglobinopathy finding.

(3) Demonstrate. upon request by the Department of Health Services. that each of its counselors successfully participates in State-approved educational programs which serve to update the knowledge and enhance the proficiency of such counselors.

(4) Have a physician with special training and experience in pediatric hematology to serve as medical director or consultant to order and interpret laboratory tests used in counseling.

(5) Have written protocols IO protect the confidentiality and security of all records containing personal information.

(6) Use only State-approved educational materials.

(7) Use any laboratory that meets the Department's standards for sickle cell hemoglobin testing.

NOTE: Authoritycited: Section 309. Health and Safety Code. Reference: Sections 325. 326 and 327. Health and Safety Code.

HISTORY

1. New section fikd by the Department of Health Services with the Secretary of State on 12-22-89 as an emergency. operative 12 22 89. Submilkd to OAL for printing only pursuant to Health and Safety Code Section 309(g) (Register 90. No. 4).

§ 6507.3. Certificate of Approval As a Sickle Cell Counselor.

(a) A sickle cell counselor shall obtain a certificate of approval from the Department of Health Services upon presentation of written evidence that he or she has:

(1) Completed a course at a sickle cell counselor training center approved by the Department with such center's endorsement of his or her ability IO function as a sickle cell counselor, and/or

(2) Successfully completed an examination or examinations which demonstrate his or her knowledge or expertise in the field, and one or more personal interviews to demonstrate an understanding of. and ability to communicate with persons who have sickle cell disease or sickle cell trait.

(b) All sickle cell counselors must provide documentation of completion of State-approved training to update skills and knowledge on an annual basis.

(c) This section shall not apply IO physicians.

NOTE: Authority cikd: Section 309. Health and SafetyCode. Reference Sections 325, 326 and 327. Health and Safety Code.

HISTORY

1. New section tiled hy the Department of Health Services with the Secretary of State on I2 22-89 as an *emergency* operative 12-22-89. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90. No. 4).
2. Repealer of section 6507.3 and renumbering of section 6507.4 to section 6507.3 filed 4 20-92 as an emergency: operative 4-20-92 (Register 92. No. 18). A Certificate of Compliance must be transmitted to OAl. 8-18 92 or emergency language will be repealed by operation of law on the following day.
3. Certificate *of* Compliance as to 4-20-92 or&r transmitted to OAL 817 92 and filed 9 28-92 (Regiskr 92. No. 40).

§ 6507.4. Voluntary Participation.

Participation by any person in a sickle cell education and counseling program in which medical information is obtained through interview. test or other ascertainment procedure shall be wholly voluntary and shall not be a prerequisite to eligibility for, or receipt of, any other services or assislance from, or lo participation in any other program.

NOTE: Autboritycited: Section 309. Health and Safety Code. Reference: Section 151, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with he Secretary of State on 12-22-89 as an emergency. operative 12-22 89. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90. No. 4).
2. Renumbering of section 6507.4 to section 6507.3 and renumbering of section 6507.5 IO section 6507.4 filed 4 20-92 as an emergency. operative 4-20-92 (Register 92, No. 18). A Certificate of Compliance must be transmitted to OAL 8-18-92 or emergency language will be repealed by operation of law on the following day.

3. Certificate of Compliance as to 4–20–92 order transmitted to OAL 8–17–92 and filed 9–28–92 (Register 92, No. 40).

§ 6507.5. Informed consent

(a) A sickle cell education and counseling program shall obtain informed consent from each adult upon whom testing or any other screening procedure is to be performed. If the person is a minor other than a newborn. informed consent shall be obtained from such child's parent or guardian. An informed consent shall be obtained from an emancipated minor without the need for parent or guardian consent.

(b) The informed consent shall be in writing in format approved by the Department and shall be signed by the person. by his or her guardian or. except in the case of an emancipated minor, by his or her parent.

NOTE: Authority cited: Section 309, Health and Safety Code. Reference: Section 151, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State an 12-22-89 as an emergency; operative 12-2249. Submitted to OAL for printing only pursuant to Health and Safety Cak section 309(g) (Register 90. No. 4).
2. Renumbering of section 6507.5 to section 6507.4 and renumbering of section 6507.6 to section 6507.5 fikd 4-20-92 as an emergency. operative 4-20-92 (Register 92, No 18). A Certificate of Compliance must be transmitted to OAL R-1 8–92 or emergency language will be repealed by operation of law on the following day.
3. Certificate of Compliance as to 4–20–92 order transmitted to OAL 8–17–92 and filed 9-28-92 (Register 92, No. 40).
4. Editorial correction of HISTORY 2 (Register 95, No. 1 8).

§ 6507.6. Approval of Hemoglobin Counseling Laboratories.

(a) All laboratories that accept specimens from an approvedsickle cell counseling program shall be in compliance with the Businessand Professions Code governing licensed clinical laboratory operations and personnel (commencing with Section 1200 of the Business and Professions Code) or be an approved public health laboratory operated in accordance with the California Health and Safety Code. Section 1000 et seq.

(b) All laboratories involved in sickle cell screening as defined in these regulations shall use a test or combination of tests with demonstrated ability to distinguish hemoglobins including F, A. S, C, D, and E. as well as the thalassemias.

(c) The State Department of Health Services shall have the responsibility of monitoring sickle cell screening laboratories coming under the scope of these regulations. Such monitoring may be accomplished by on–site inspections and proficiency testing, or any other effective method. The Department may deny, revoke. or suspend the approval of any laboratorywhichdoesnotcomplyorcontinuetocomplywith the above qualifications.

NOTE Authority cited: Sections 20X(a). 309 and 32.5, Health and Safety Code. Reference: Sections 325 and 327, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 12–22–89 as an emergency; operative 12–22–89. Submitted to OAL for printing only pursuant to Health and Safety Code section 309(g) (Register 90. No. 4).
2. Renumbering of section 6507.6 to section 6507.5 and renumbering of section 6507.7 to section 6507.6 Ckd 4-20-92 as an emergency, operative 4–20–92 (Register 92. No. 18). A Certificate of Compliance mud be transmitted to OAL 8–18–92 or emergency language will be repeakd by operation of law on the following day.
3. Certificate of Compliance as to 4-20-92 order transmitted to OAL 8–17–92 and filed P-28-92 (Register 92. No. 40).

§ 6507.7. Sickle Cell Trait Follow-Up Vendor.

(a) A sickle cell trait follow-upvendor shall mean any sickle cell education and counseling program that is:

(I) approved under this subchapter, and

(2) signs a vendor agreement to provide services in accordance with Department policies. including a fee schedule provided by the Department. The Department may obtain and provide reimbursements for any or all follow-up services authorized as a result of newborn sickle cell screening from such approved vendors.

NOTE: Authority cited: Section 309. Health and Safety Code. Reference: Sections 325 and 326. Health and Safety Code.

HISTORY

1. Renumbering of section 6507.7 to section 6507.6 and new section filed 4–20–92 as an emergency; operative 4–20–92 (Register 92. No.18). A Certificate of Compliance must be transmitted to OAL 8–18–92 or emergency language will be repealed by operation of law on the following day.
2. Certificate of Compliance as to 4–20–92 order transmitted to OAL R-17-92 and filed 9-28-92 (Register 92. No. 40).

§6508. Fee Collection.

(a) Perinatal licensed health facilities and birth attendants shall obtain from the Department a sufficient supply of specimen collection forms to permit collection of a blood specimen from each newborn required to be tested under these regulations.

(b) The Department shall collect a fee for each specimen record form provided and a program participation fee for all services provided The fee for a specimen record form shall be one (I) dollar and for program services forty-one (41) dollars except for a comprehensive prepaid group practice direct health care service plan with 20.000 or more births in the last completed calendar year for which complete statistics are available. which elects to provide testing. follow-up and/or counseling services to its members. The fee for such plans shall be. equal to the Department's cost of administration of the newborn screening program. to be determined by reducing the forty-one (41) dollar program service fee by the annual statewide average per infant contracted cost of laboratory testing. follow–up and/or counseling services rendered during the previous fiscal year. In order to qualify for this special fee a medical group serving a comprehensive prepaid group practice direct care service plan with 20,000 or more births shall sign a written agreement which contains the same standards and conditions, except as to payment or where specifically waived, as are applicable to the newborn screening laboratories and area genetic centers, adhere to the regulations governing the program. and to submit to monitoring and evaluation of compliance. Failure to comply with these conditions after being given written notification and thirty (30) days to correct deviations shall result in loss of the option In the event the option is lost the State shall designate appropriate contractors to provide services.

'The provisions of this section shall not apply if the newborn is part of a State-approved demonstration program.

(c) Birth attendants and physicians attending newborns who are under six days of age and who were not born in perinatal licensed health facilities and not subsequently admitted to perinatal licensed health facilities shall obtain a sufficient supply of specimen record forms to permit collection or shall arrange for a collection of a blood specimen from each such newborn attended.

(d) Birth attendants and physicians attending newborns and perinatal licensed health facilities shall not charge parents or third parties responsible for medical cam coverage fees for participation in the newborn screening program in addition to those specified in this section. except for reasonable fees for costs of blood specimen collection and handling which shall not exceed six (6) dollars.

(e) The perinatal licensed health facility shall make available to the responsible physician. at no additional charge. specimen collection services or a specimen record form for obtaining either a repeat specimen for an inadequate specimen or a specimen on a newborn discharged without the test having been obtained.

(f) Birth attendants and physicians submitting a blood specimen for newborn screening on a form other than those approved by the Department shall be charged a handling fee of five (5) dollars in addition to the usual fee for program services and specimen record form specified in (b) above for each such specimen.

NOTE: Authority cited: Section 125000(h)(j), Health and Safety Code. Reference: Sections 125000(b) and 125005. Health and Safety Code.

HISTORY

1. New action tikd I 1–2 1-86; effective thirtieth day thereafter (Register 86. No. 47).
2. Amendment filed 12–6–90 as an emergency print only; operative 12-6-M (Register 91, No. 14). A Certificate of Compliance must be transmitted to OAL

by April 5, 1991, or emergency language will be repealed by operation of law on the following day.

3. Certificate of Compliance as to 12-6-90 order transmitted to OAL 3-19-91 and filed 4-8-91 (Register 91, No. 19).

4. Amendment filed 8-7-91 by the Department of Health Services with the Secretary of State, operative 8-7-91. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code section 309 (Register 91, No. 50).

5. Amendment of subsection (b) filed 6-30-92 with Secretary of State by the Department of Health Services; operative 7-1-92. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code sections 289.7(b) and 309(h) (Register 92, No. 27).

6. Certificate of Compliance as to 6-30-92 order transmuted to OAL 10-20-92 and filed 11-20-92 (Register 92, No. 47).

7. Editorial correction of HISTORY 5. (Register 92, No. 47)

8. Amendment of subsections (b) and (f) and amendment of NOTE filed 6-6-97 as an emergency; operative 6-6-97 (Register 97, No. 24). This regulatory action is deemed an emergency exempt from OAL review and was filed directly with the Secretary of State pursuant to Health and Safety Code section 125000(h). These amendments shall remain in effect until rewed or repealed by DHS pursuant to Health and Safety Code section 125000(j).

§ 6510. Rhesus (Rh) Hemolytic Disease of the Newborn.

(a) Medical staffs of hospitals and physicians thereof shall in providing for the care of pregnant women determine that a blood specimen has been obtained for the determination of rhesus (Rh) blood type or shall obtain or cause to be obtained a blood specimen within 24 hours of termination of pregnancy whether by delivery or by spontaneous or therapeutic abortion for this purpose as required by Article 2.7, Chapter 2, Part 1 of Division I of the Health and Safety Code.

(b) All cases, or suspected cases of rhesus (Rh) hemolytic disease of the newborn, shall be reported to the Department of Health Services. Every patient diagnosed in any licensed hospital as having such condition shall be reported by the hospital on the form provided by the Department for this purpose. The hospital shall notify the physician making the diagnosis that such a report has &en filed.

NOTE: Authority cited: Sections 1511,208 and 306(b), Health and Safety Code. Reference: Sections 204,305 and 306, Health and Safety Code.

HISTORY

New section filed 3-16-70; effective thirtieth dny thereafter (Register 70, No. 12).

2. Amendment of subsection (a)(1) filed 2-2-71; effective thirtieth day thereafter (Register 71, No. 6).

3. Editorial correction filed 11-5-84 (Register 84, No. 45).

Article 2. Testing of Pregnant Women for Heritable and Congenital Disorders

§ 6521. Definitions.

(a) Neural Tube Defects of the Fetus. "Neural lube defects of the fetus" means any malformation of the fetus caused by failure of the developing spine and skull to properly close. Examples are spina bifida and anencephaly.

(b) Birth Defects. "Birth defects" means any functional or structural defect caused by failure or error in the development of a fetus that is capable of being prenatally detected and for which the Department has provided a surveillance or screening program including but not limited to neural tube defects, ventral wall defects. and chromosomal defects.

(c) Expanded AFP Prenatal Screening for Birth Defects. "Expanded AFP prenatal screening for birth defects" means the sequence of screening tests of initial and repeat blood tests and where medically indicated differential diagnostic screening tests and procedures authorized by the Department and provided by department-approved vendors.

(d) Differential Diagnostic Screening Tests and Procedures. "Differential diagnostic screening tests and procedures" means those additional screening tests. methods. examinations or activities which are performed consequent to a positive blood screening test and which are used to distinguish between the presence of a birth defect of the fetus and other causes of positive blood screening tests.

(e) Gestational Age. "Gestational age" shall be defined as the number of days elapsed since the first day of the last normal menstrual period. Gestational age may be calculated as the number of days from known or suspected conception plus 14 days or by ultrasound examination and measurements.

(f) Alpha-fetoprotein. "Alpha-fetoprotein" means the protein substance in maternal serum and amniotic fluid. the concentration of which is tested to determine the probability that the fetus has a neural tube defect. For the purpose of these regulations. alpha-fetoprotein may he abbreviated and referred to as "AFP," maternal serum alpha-fetoprotein may be abbreviated and referred to as "MS-AFP," and amniotic fluid alpha-fetoprotein may be abbreviated and referred to as "AF-AFP."

(g) Analyte. "Analyte" means any constituent or substance the concentration of which is related to the presence of a birth defect and is analyzed and reported by prenatal screening laboratories as part of a departmentally provided or administered prenatal screening program including but not limited to alpha-fetoprotein, human chorionic gonadotrophin and estriol.

(h) Method. "Method" means the steps and procedures used in a laboratory to measure the concentration of analytes in samples of maternal serum or amniotic fluid. Instruments, devices and reagents used are included in this definition.

(i) Expanded AFP Prenatal Birth Defects Screening Laboratory. "Expanded AFP prenatal birth defects screening laboratory" means a laboratory approved hy the Department to conduct prenatal screening laboratory tests to determine the concentration of analytes and perform other analysis related to birth defects specified as part of state administered testing.

(j) Clinician. "Clinician" means physician, physician assistant, nurse midwife, nurse practitioner or any other person licensed or certified by the State to provide prenatal care to pregnant women or to practice me& cine.

(k) Prenatal Diagnosis Center. "Prenatal diagnosis center" means any facility in California which is approved by the Department to provide differential diagnostic tests and procedures for the prenatal evaluation or detection of genetic diseases. disorders. and birth defects of the fetus.

(l) Initial Specimen. "Initial specimen" means the first adequate specimen collected from a pregnant woman pursuant to these regulations.

(m) Initial Screening Positive Test. "Initial screening positive test" means an initial screening test of a specimen which gives a positive result as defined by the Department for reporting purposes pursuant to these regulations.

(n) Inadequate Specimen. "Inadequate specimen" means a blood specimen collected from a pregnant woman which is not suitable in quality or quantity, was collected before the 105th or after the 140th day of gestation, or was not documented with the clinical information necessary for test result interpretation to perform valid prenatal screening for birth defects of the fetus.

(o) Repeal Specimen. "Repeal specimen" means a blood specimen collected from a pregnant woman following the screening laboratory report that a previously collected blood specimen was either inadequate or that the screening test results were screening positive or inconclusive as defied by the Department.

(p) An Expanded AFP follow-up vendor shall mean any facility, clinic. institution. health maintenance organization. or physician that:

(l) submits documentation verifying that it meets the standards published by the Department for approval as a comprehensive prenatal diagnosis center entitled: Prenatal Diagnosis Center Standards and Definitions 1997. This document in its entirety is hereby incorporated by reference in this section;

(2) has had the documentation verified hy a state visit or;

(3) has had experience in the provision of follow-up of women with abnormal MS-AFP results asdelined by California's MS-AFP Program prior to April 1, 1992; and

(4) receives notification of approval as a Prenatal Diagnosis Center; and

When notified that a blood specimen is inadequate for testing, the c an shall make a reasonable effort to have an adequate specimen obtained as soon as possible hut not more than five (5) days after such notification.

(g) For each woman in theircare who was prenatally screened for birth defects of the fetus and who had an initial screening positive test, the clinician shall:

(I) Inform the woman that authorized follow-up services are available at Expanded AFP Follow-up Vendors. and that the program participation fees or lahoralory test fee covers the authorized services.

(2) Report on the form provided by the Department for this purpose. within 30 calendar days of the end of the pregnancy, the outcome of pregnancy and status of each fetus. or infant resulting therefrom.

(h) The test results shall he confidential so that such information shall only he released with the knowledge and specific written consent of the woman tested. Persons authorized by the Department to conduct and monitor screening and/or to provide and monitor differential diagnostic follow-up services shall he provided information without necessity of specific written consent.

(i) Recognizing the strict gestational and time limits wherein prenatal detection of birth defects of the fetus is feasible. clinicians shall make every reasonable effort to schedule screening and differential diagnostic tests and procedures appropriately with respect IO the gestational dates of the pregnant woman.

(j) Willful or repeated failure to comply with these regulations shall he referred by any person having knowledge of noncompliance IO the appropriate licensing authority.

NOTE: Autboritycited: Sections 12500 and 125070, Health and Safety Code. Reference: Sections 124980 (b), (c), (d), (h), (j) and 12.5070, Health Safety Code.

HISTORY

1. w section filed by the Department of Health Services with the Secretary of e on 4-746 as an emergency. effective upon filing. Submitted to OAL for .nting only pursuant to Government Code Section I 1343.8 (Register 86, No. 16).
2. New subsection (j) filed by the Department of Health Services with the Secretary of State on 6–16–88 as an emergency; effective 7–1–88. Submitted to OAL for printing only pursuant to Government Code Section I 1343.8 (Register 88, No. 27).
3. Certificate of Compliance as to 6–16–88 order transmitted to OAL 10–19–88 and filed I I-18-88 (Register 88, No. 48).
4. Amendment filed 8–7–91 by the Department of Healtb Services with the Secretary of State, operative 8–7–91. Submitted to OAL as an emergency for printing only pursuant to Healtb and Safety Code section 309 (Register 9 1, No. 50).
5. Amendment of section and NOTE filed 6-14-96 as an emergency. operative 6–14–96. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 96, No. 24).
6. Editorial correction of HISTORY 5 (Register 97. No. 12).
7. Amendment of subsections (a),(c),(d)(l) and (d)(2), repealer of subsection (e). subsection relettering. and amendment of newly designated subsection (g)(l) filed 3-l 4-97 by the Department of Healtb Services with the Secretary of State; operative F-14-97. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code section 125000 (Register 97. No. 12).

§ 6529. Program Participation Fee.

(a) The Department shall collect an all-inclusive program participation fee for each screening service program. The fee for maternal serum alpha fetoprotein screening service for neural tube defects only shall be fifty-seven (57) dollars. The fee for maternal serum alpha fetoprotein and one or more additional analytes screening service for NTD and Down Syndrome shall be one hundred and fifteen (1 15) dollars. The fee shall be paid to the Department by the woman being tested or hy any third party which is legally responsible for her care incbdingany health care service plan. managed health care plan. managed care plan, prepaid health plan or prepaid group practice health care service plan as defined in or licensed cordance with Health and Safety Code sectitm 1340 et seq.

(b) Health care providers which contract with a prepaid group practice health care service plan that annually has at least 20,000 births among its membership. may provide, without contracting with the Department, any or all of the testing and counseling sew ices required to he provided under this section. if the services meet quality standards established hy the Department and the plan pays that portion of a fee established under this section which is directly attributable to the Department's cost of administering the testing or counseling service and any required testing or counseling services provided hy the state for plan members during the previous fiscal year. This option must be executed under terms of a written agreement. Payment hy the plan shall he deemed to fulfill any obligation the provider or the provider's patient may have to the Department to pay 3 fee in connection with the testing or counseling service.

Non Authority cited: Sections 125070 and 125000(h)(j), Health and Safety Code. Ref erence Sections 125000(b), 125005, 125050, 125055, 125060 and 125065, Health and Safety Code.

HISTORY

1. New section filed hy the Department of Health Services on 4–7–86 as an emergency; effective upon filing. Submitted to OAL for printing only pursuant to Government Code section I 1343.8 (Register 86. No. 16).
2. Amendment of subsection (a) filed by the Department of Health Services with the Secretary of State on 6–16–88 as an emergency: effective 7-1-88. Submitted to OAL for printing only pursuant to Government Code section I 1343.8 (Register RR. No. 27).
3. Certificate of Compliance as to 6–16–88 order transmitted to OAL 10–19–88 and fikd I I-18-88 (Register XX. No. 48).
4. Amendment tiled R-7-9 I hy the Department of Health Sew ices with the Secretary of State; operative 8–7–91. Submitted to OAL as an emergency for printing only pursuant to Healtb and Safety Code section 309 (Register 91, No. 50).
5. Amendment of subsection (a) filed 6–30–92 with Secretary of State by the Department of Health Services; operative 7-1-92. Submitted to OAL as an emergency for printing only pursuant IO Healtb and Safety Code sections 289.7(b) and 309(h) (Register 92, No. 27).
6. Certificate of Compliance as to 6-30-92 or&r transmitted to OAL 10–20–92 and filed I I-20-92 (Register 92, No. 47).
7. Editorial correction of HISTORY 5. (Register 92, No. 47).
8. Amendment of subsections (a) and (b) and amendment of NOTE filed 6–6–97 as an emc rgency; operative 6-6-97 (Register 97, No. 24). This regulatory action IS deemed an emergency exempt from OAL review and was fikd directly with the Secretary of State pursuant to Health and Safety Code sections I 25000(h) and 125070(b). These amendments shall remain in effect until revised or repealed by DHS pursuant to Health and Safety Code sections 125000(j) and 125070(c).

§ 6531. Reporting of Neural Tube Defects.

(a) All cases of neural tube defect in a fetusoran infant under one year of age shall be reported to the Department. Neural tube defects shall mean any malformation of the fetus caused by the failure of the developing spine and skull to properly close.

(b) This report shall be made:

(I) By the health facility in which the case is initially diagnosed;

(2) By the physician making the initial diagnosis if the case is not diagnosed in a health facility:

(3) Within 30 calendar days of the initial diagnosis;

(4) On the form to be provided by the Department for this purpose.

NOTE: Authority cited: Section 289.7. Health and Safety Code. Reference: Section 289.7. Health and Safety Code.

HISTORY

1. New section tiled by the Department of Health Services with the Secretary of State on 10–9–85 as an emergency; effective upon filing. Submitted to OAL for printing only pursuant to Government Code Section I 1243.8 (Register 85, No. 45).

3 6532. Reporting of Chromosomal Disorders.

(a) All cases of Down's syndrome a other chromosomal defects in a fetus or an infant under one year of age shall be reported to the Department. Chromosomal defects shall mean any abnormality in structure or number of chromosomes.

(b) This report shall be made:

(I) by the cytogenic laboratory performing the chromosomal analysis or by the physician making the diagnosis:

(2) within 30 calendar days of the initial diagnosis:

(3) on a form to he provided by the Depar tment for this purpose.

NOTE: Authority cited: Section 309. Health and Safety Code. Reference: Section 309. Health and Safety Code.

HISTORY

1. New section fikd by the Department of Health Services with the Secretary of State on 2-24-89 as an emergency; operative on 3–1–89. Submitted to OAL for printing only pursuant to Government Code Section I 1343.8 (Register 89, No. 10).

(5) signs a vendor agreement to provide such services in accordance with Department policies including a fee schedule published hy the Department entitled: Vendor Agreement March I. 1996. and incorporated by reference in these regulations. The Department may obtain and provide reimbursement for any or all follow-up services authorized as the result of MS–AFP screening from any or all such approved vendors

NOTE: Authority cited: Sections 125000 and 125070, Health and Safety Code. Reference: Sections 124975–125050 and 125070, Health and Safety Code.

HISTORY

1. New article 2 (sections 6521–6529, not consecutive) filed by the Department of Health Services with the Secretary of State on 4–7–86 as an emergency, effective upon filing. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register X6. No. 16).
2. Amendment of subsection (h) filed by the Department of Health Services with the Secretary of State on 6-16-88 as an emergency; effective 7-l-88. Submitted to OAL for printing only pursuant to Government Code section 11343.X (Register X8. No. 27).
3. Certificate of Compliance as to 6–16–88 order transmitted to OAL 10–19–88 and filed 11-18-88 (Register 88, No. 4X).
4. New subsections (n)–(n)(3) and amendment of NOTE filed 4–20–92 as an emergency; operative 4–20–92 (Register 92. No. IX). A Certificate of Compliance must be transmitted to OAL 8-1 8-92 or emergency language will be repealed by operation of law on the following day.
5. Certificate of Compliance as to 4–20–92 order transmitted to OAL 8-1 7-92 and filed 9-28-92 (Register 92. No. 40).
6. Amendment of subsection (n)(l). new subsections (n)(2) and (n)(4). subsection renumbering and amendment of NOTE filed 10-1-92 as an emergency; operative 10–1–92 (Register 92. No. 40). Submitted to OAL for printing only pursuant to Government Code section 11343.8.
7. Certificate of Compliance as to 10–1–92 order filed 3-3-92 (Register 93, No. 10).
X. Amendment of section and NOTE filed 6–14–96 as an emergency; operative 6–14–96. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 96, No. 24).
Y. Editorial correction of HISTORY 8 (Register 97. No. 12).
10. Amendment of subsection (p)(1) filed 3–14–97 by the Department of Health Services with the Secretary of State; operative 3–14–97. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code section 125000 (Register 97, No. 12).

§ 6523. Expanded AFP Prenatal Birth Defects Screening Laboratories and Analytical Methods.

(a) The Department shall approve Expanded AFP prenatal birth defects screening laboratories. Such laboratories shall be licensed as clinical laboratories under Divisitm 2, Chapter 3 (commencing with Section 1200) of the Business and Professions Code.

(b) Approved Expanded AFP prenatal birth defects screening labora tories shall be limited to the following:

(1) A laboratory that shall have obtained a contract from the Department under applicable laws and regulations to provide laboratory services in sufficient volume to provide the prenatal birth defects screening test to all pregnant women in a designated geographic areadeftted by the Department. plus an emergency testing capacity that will be specified by contract. The Department will define not more than 6 geographic areas and may combine geographic areas if necessary to reduce costs or assure statewide coverage.

(2) A laboratory exclusively serving a comprehensive prepaid group practice or health care service plan with 25,000 or more births in the last completed calendar year for which complete statistics are available may beapproved for tcstingconsistent with the terms of a mutually acceptable contract for services.

(c) Expanded AFP prenatal birth defects screening laboratories ap proved by the Department shall comply with all laboratory standards for quality assurance issued by the Department and shall participate in a proficiency testing program approved and/or conducted by the Department and shall maintain levels of performance acccptahle to the Department.

(d) Analytical methods to be used in the measurement of each analyte concentration in maternal serum shall be designated and/or approved by the Department.

(e) Analytical methods to be used in the measurement of the analyte concentration in amniotic fluid, and other adjunctive tests performed on amniotic fluid shall be designated and/or approved by the Department.

NOTE: Authority cited: Sections 125000(e) and 125070, Health and Safety Code. Reference: Sections 124980, 125000(e) and 125070, Health and Safety Code.

HISTORY

1. New section filed by the Department of Health Services with the Secretary of State on 4–7–86 as an emergency; effective upon filing. Submitted to OAL for printing only pursuant to Government Code Section 11343.8 (Register 86, No 16).
2. Amendment of section heading, section and NOTE filed 6–14–96 as an emergency; operative 6–14–96. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 96. No. 24)
3. Editorial correction of HISTORY 2 (Register 97. No. 12).
4. Repeal of subsections (b)(3) and (f) filed 3–14–97 by the Department of Health Services with the Secretary of State: operative 3–14–97. Submitted to OAL as an emergency for printing only pursuant to Health and Safety Code section 125000 (Register 97. No. 12).

§ 6525. Prenatal Diagnosis Centers and Laboratories.

The Department shall approve prenatal diagnosis centers and prenatal diagnosis methods and Expanded AH' Birth Defect Screening Laboratories and laboratory methods and shall institute such quality control and proficiency testing as is necessary to assure the accuracy of testing. No laboratory shall offer or provide prenatal birth defect screening diagnostic tests on California residents without having obtained prior approval from the Department.

NOTE: Authority cited: Sections 125050, 125055 and 125070, Health and Safety Code. Reference: Sections 124980, 125000 and 125070. Health and Safety Code.

HISTORY

1. New section tiled hy the Department of Health Services with the Secretary of State on 4-7-86 as an emergency; effective upon filing. Submitted to OAL for printing only pursuant to Government Code Section 11343.8 (Register 86, No. 16).
2. Amendment of section heading, section and NOTE filed 6–14–96 as an emergency; operative 6–14–96. Submitted to OAL for printing only pursuant to Government Code section 11343.8 (Register 96. No. 24).
3. Editorial correction of HISTORY 2 (Register 97. No. 12).

§ 6527. Clinicians.

(a) Clinicians shall provide or cause to be provided to all pregnant women in their care before the 140th day of gestation, or before the 126th day from conceptiat, as estimated by medical history or clinical testing. infomtation regarding the use and availability of prenatal screening for birth defects of the fetus. This information shall be in a format to be provided or approved by the Department and shall be given at the first prenatal visit and discussed with each pregnant woman.

(b) The provisions of subsection (a) shall not apply if the pregnant woman has completed more than 140 days of gestation or 126 days post conception. as estimated by medical history or clinical testing. and this fact is entered in the medical record.

(c) Clinicians shall cause to be provided to all pregnant women who. after being provided with the information pursuant tosubsection (a). voluntarily request prenatal screening for birth defects of the fetus, the opportunity, the circumstances of which are to be documented in the medical record. to read and sign an informed consent document in a format provided or approved by the Department.

(d) If the pregnant woman consents to testing, the clinician shall arrange for prenatal screening directly or by referral to another clinician by:

(I) Fully and accurately completing all required specimen collection forms provided by the Department for this purpose;

(2) Collecting or arranging for the collection of an initialspecimen following state directions for collection provided;

(3) As soon as possible. but within 24 hours of collection. place or cause to be placed all initial and repeat specimens in the channel of transmittal to the designated Expanded AFP prenatal birth defects screening laboratory.

(c) Blood collection forms and blood collection and mailing kits supplied by the Department shall not be copied. printed. reproduced. acquired. purchased, substituted or distributed other than as specified for use in the Expanded AFP Prenatal Birth Defects Screening Program administered by the Department.

DEPARTMENT OF HEALTH SERVICES
14/744 P Street
P. 0. Box 942732
Sacramento, California 94234-7320
(916) 654-8076

July 28, 1998

MMCD ALL PLAN LETTER 98-06

TO: All Managed Care Plans

SUBJECT: CALIFORNIA CHILDREN SERVICES NUMBERED LETTERS 01-0298 AND 09-0598

Please find enclosed for your information two California Children Services (CCS) numbered letters (NL) which are directed to County CCS programs.

NL 01-0298 describes CCS' policy for authorization of automobile orthopedic positioning devises for CCS eligible children. NL 09-0598 describes CCS' policy for authorization of Early and Periodic Screening, Diagnosis and Treatment Supplemental Services request, including hourly nursing.

These letters are being sent for your information only to help you remain current regarding CCS authorization procedures and to facilitate care coordination efforts between managed care plans and CCS.

Sincerely,

Susanne Hughes for

Ann-Louise Kuhns, Chief
Medi-Cal Managed Care Division

Enclosure

STATE OF CALIFORNIA—HEALTH AND WELFARE AGENCY

DEPARTMENT OF HEALTH SERVICES
P STREET
OX 942732
SACRAMENTO CA 94234-7320
(916) 654-0832
(916) 654-0476 TDD Relay

N.L. : 01-0298
February 11. 1998
Index: Durable Medical Equipment

TO: All California Children Services (CCS) County Program Administrators. Medical Consultants, Chief/Supervising Therapists. Medical Therapy Units. State Regional Office Administrators. Medical and Therapy Consultants

SUBJECT: DURABLE MEDICAL EQUIPMENT (DME) GUIDELINES ADDENDUM: AUTOMOBILE ORTHOPEDIC POSITIONING DEVICES (AOPDS)

Introduction

CCS authorizes purchase of DME items that are medically necessary to treat a child's CCS-eligible medical condition. If the child is a Medi-Cal-eligible beneficiary. the CCS program authorizes DME that is deemed medically necessary and is a benefit of the general Medi-Cal program: or if the DME is not a general Medi-Cal program benefit, may request authorization as an Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) supplemental service.

The CCS DME Guidelines were established in 199'. to provide criteria for purchase of DME-Rehabilitation items that are considered medically necessary benefits cf the CCS program. In those guidelines. AOPDs. or non-standard (commercially available) car seats and harness/vests. were categorized as items that could be useful for the family. but were not considered medically necessary CCS benefits. CCS now recognizes there are instances when these items would be medically necessary to treat the child's CCS-eligible condition.

Policv

Effective the date of this letter. AOPDs are a benefit of the CCS program when they meet the criteria applicable to the item listed in the enclosed addendum to the DME guidelines. CCS will not authorize the purchase of standard. commercially available car seats or vests/harnesses that are required by California state law for children are under 4 years of age and under 40 pounds. If the child is Medi-Cal eligible. the request must be submitted as an EPSDT supplemental services request in order for the equipment to be reimbursable by Medi-Cal.

Policy Guidelines

Requests for AOPDs must be reviewed and approved by the county CCS program medical consultant or designee or the state CCS regional office therapy consultant prior to authorization. Request for authorizations must be accompanied by a current prescription. a current medical report that justifies the medical necessity of the item, and a physical therapy and/or occupational therapy assessment that addresses the criteria in the DME guidelines for the item.

If you have any questions regarding this change in policy, please contact Jeff Powers at (916) 657-0834. Thank you for your attention to this matter.

Maridte A. Gregory, M.D.. Chief
Children's Medical Services Branch

Enclosure

CCS Guide For Purchase Of
Durable Medical Equipment

Positioning

Automobile Orthopedic Positioning Devices (AOPD)
Car Seats
Harnesses

Equipment	Medical Necessity	Criteria	Related Considerations
Automobile Orthopedic Positioning Devices (AOPD)			* CCS will purchase only 1 AOPD over a lifetime.
Car seats	Requires maximal to moderate postural suppon to maintain a safe sitting position during transportation	Child must be over 4 years of age and either over 40 pounds or over 40 inches in length. and must meet one of the followmg criteria: 1) Has moderate-minimal trunk control sitting ability, moderate to minimal lateral head control and requires total postural support 2) At risk for breathing complications as a result of poor trunk control or alignment 3) Presence of a skeletal deformity requiring total postural suppon for safe transportation	* The child's length. width or physical deformity precludes use of a commerctally available car seat * A harness or vest will not provide the child with . enough stability to remain in proper alignment or allow for safe transport * Child cannot be transported in wheelchair because the family does not own appropriate vehicle to allow this.
Harnesses Vests	Same as car seats	ihild must be over 4 years of age and either over 40 pounds or over 40 inches in length and meets one of the three criteria for car seats, or due to deformity or surgical corrections must be nanspotted in other than an upright position.	* The childs' physical deformity or trunk instability precludes use of a standard seat belt or commerctally available vest or harness. * A standard seat belt or commercially available vestharness will not provide the child with enough stability to remain in proper alignment or allow for safe transport. * Child cannot be transported in wheelchair because the family does not own appropnate vehicle to allow this.

STATE OF CALIFORNIA-HEALTH AND WELFARE AGENCY PETE WILSON, Governor

DEPARTMENT OF HEALTH SERVICES
1/744 P STREET
.J. BOX 942732
SACRAMENTO, CA 94234-7320

(916) 653-3480
(916) 654-0476 TDD/Relay

May 26, 1996

N.L. : 09-0598
Index: EPSDT Supplemental Services
Subject: Eatiy and Periodic Screening, Diagnosis, and Treatment (EPSDT) Supplemental Services (SS)

TO:' California Children Services (CCS) Program Administrators, Medical Consultants, CCS Regional Office Medical Consultants, and CCS State Program Consultants, and Nurse Consultants

SUBJECT: EARLY AND PERIODIC SCREENING, DIAGNOSIS, AND TREATMENT (EPSDT) SUPPLEMENTAL SERVICES (SS)

The purpose of this numbered letter is to clarify the procedure for EPSDT SS requests for those CCS medically-eligible children who are **Medi-Cal,** full scope, no share of cost.

ALL EPSDT SS REQUESTS EXCEPT HOURLY NURSING SERVICES

ALL EPSDT SS requests for a **CCS-eligible** child with **Medi-Cal,** full scope, no share of cost, with the exception of requests for long term hourly nursing services in the home, are to be sent to:

EPSDT SS Coordinator
Children's Medical Services Branch
714 P Street, Room 350
P.O. Box 942732
Sacramento, CA 94234-7320
Office: (916) **654-0499**
FAX: (916) 654-0501

Enclosed are all the forms necessary to submit an EPSDT SS request. Please remember that the ***EPSDT SS WORKSHEET*** must accompany each request. The check-off lists are for CCS staff to use in preparing the request. The other forms are provider forms and must be completed by the provider and returned to the local county CCS program. When preparing an EPSDT SS request, please refer to California Code of Regulations, Title 22, Division 3, Health Care Services, Sections **51184, 51340, 51242,** and 51013. Section 51340(e) specifically addresses the type of documentation that must be submitted with a request. When the CCS program has gathered all the necessary information to support the EPSDT SS request, the request may be submitted to the EPSDT SS **Cocrdinators** at the State CMS office.

EPSDT SS HOURLY NURSING SERVICE REQUESTS

All requests for EPSDT SS long term hourly or shift nursing services in the home are to be submitted by the **provider** on the format prescribed by Medi-Cal to:

In-Home Operations Intake Unit
1801 Seventh Street
P.O. Box 942732
Sacramento, California
94234-7320
(916) 324-5940
FAX (916) 324-0297

The In-Home Operations Unit does the review and determination for EPSDT Supplemental Services long term hourly nursing services in the home and continues to do case evaluation for the Waiver Services such as the In-Home Medical Care Waiver, Nursing Facility Waiver, and the Model Waiver.

If you have any questions, please contact Sally Paswaters, R.N., at (916) 653-8784, or Galynn Plummer-Thomas, R.-N., at (916) 6533480.

Elizabeth N. Hyman
for

Maridee A. Gregory, M.D., Chief
Children's Medical Services Branch

Enclosures

Enclosures

A. EPSDT SS WORKSHEET (which must accompany each EPSDT SS request)
B. EPSDT SUPPLEMENTAL BENEFITS REQUEST FOR AUDIOLOGY SERVICES
C. EPSDT SUPPLEMENTAL SERVICES REQUEST FOR MEDICAL FOODS
D. EPSDT SUPPLEMENTAL SERVICES REQUEST FOR MEDICAL NUTRITION ASSESSMENT.
E. EPSDT SUPPLEMENTAL SERVICE REQUEST FOR MEDICAL NUTRITION THERAPY
F. PULSE OXIMETER PROVIDER FORM
G. PULSE OXIMETER CHECK LIST
H. OCCUPATIONAL THERAPY REQUEST DOCUMENTATION CHECKLIST
I. DURABLE MEDICAL EQUIPMENT REQUEST DOCUMENTATION CHECKLIST
J. REQUEST FOR MENTAL HEALTH ASSESSMENT ONLY and the REQUEST TO PROVIDE TREATMENT
K. MEDICAL OPERATIONS DIVISIONS DEFER THE TAR TO REFER TO CCS
L. MEDI-CALOPERATIONS DIVISION HEADS UP LETTER TO CCS THAT A PROVIDER HAS BEEN REFERRED TO OBTAIN THE SERVICES FROM CCS

State of California—Health and Welfare Agency

Department of Health Services
Children's Medical Services Branch

CHILDREN'S MEDICAL SERVICES (CMS) BRANCH
CALIFORNIA CHILDREN SERVICES (CCS) PROGRAM

EARLY AND PERIODIC SCREENING, DIAGNOSIS, AND TREATMENT (EPSDT) SUPPLEMENTAL SERVICES (SS) WORKSHEET

ID #: _____
TO BE FILLED IN BY CMS CENTRAL OFFICE

Patient Name: _____ DOB: _____
(Last, First, Middle Initial)

CCS County/or Regional Office: _____ CCS Number: _____

Social Security Number: _____ Medi-Cal Number: _____

CCS Medically Eligible Condition Related to EPSDT SS Request: _____

EPSDT SS Requested: _____

If Applicable, Include Frequency and/or Duration of EPSDT SS: _____

If Applicable, Indicate Cost of Supply, Product, or Equipment: _____

Date This EPSDT SS *Request* Was Received in Your CCS Office: _____

Has County already authorized this request?, Yes ☐ No ☐ Dates: _____

Is This Request a Renewal of a Previously Authorized EPSDT SS? Yes ☐ No ☐

Name of the Provider and/or Facility Providing EPSDT SS: _____

	Yes	No
1. EPSDT SS request is to treat a CCS-eligible condition/or complication thereof? If no, attach justification of EPSDT SS request.	☐	0
2. EPSDT SS is a Medi-Cal benefit?	0	0
3. EPSDT SS is a CCS benefit?	0	0
4. Provider requesting to provide EPSDT SS is an enrolled Medi-Cal provider?	0	0
5. Provider requesting to provide EPSDT SS is a CCS paneled provider?	0	0
6. Provider requesting to provide EPSDT SS is employed by an enrolled Medi-Cal provider?	0	0
7. Is there alternative care which is less costly than the EPSDT SS? If yes, identify alternative care and its cost: _____	0	☐
8. Is patient an In-Home Operations client?	0	0

County Recommendation(s):	Central Office Decision:	**To Be Filled in By CMS** Central Office
		Committee (Comm) Code:
		Date Presented to Comm:
By:	By:	Comm Decision Code:
Phone #:	Phone #:	Comm Decision Date:
FAX #:		Date County Notified:
Date:	Date:	Consultant Code:

Mail or Fax the required documents listed below to:

- EPSDT SS Worksheet
- Supporting documentation that describes how the EPSDT SS request meets the definition of Section 51340(e), TITLE 22.
- Form for specific EPSDT SS category, completed by providers. for nutrition, pulse oximeter, mental health, dental, and audiology services.

Children's Medical Services Branch
EPSDT Coordinator
714 P Street, Room 350
P.O. Box 942732
Sacramento, CA 95814
Office: (916) 654-0499 or (916) 654-0832
FAX: (916) 654-0501

MEDI-CAL EPSDT SUPPLEMENTAL SERVICES, REQUEST

(Audiology services, cochlear implant, ALDs and nonconventional hearing aids)

(CCS NOTE: Include this form with the CCS EPSDT request form.)

. DATE OF REQUEST: _____

NAME: _____ DOB: _____ MEDI-CAL# _____

SUMMARY OF CONDITIONS FOR THIS REQUEST:

Primary diagnosis: _____

Other dx: _____

Age of onset: _____ Etiology: _____

Functional impairment(s): _____

_____

CURRENT **STATUS:** Physical health: _____

Otological: _____

Audiological: _____

Amplification: _____

Education Placement: _____

Communication level and mode: _____

_____

Cognitive ability/cooperation: _____

Describe all current program/treatment enrollment: _____

_____

_____

PATIENT/FAMILY EXPECTATIONS: _____

_____

PRIOR TREATMENT FOR **THIS CONDITION:** _____

_____

_____

WHY ARE -AL SERVICES NEEDED?: _____

_____

_____

TREATMENT PLAN:

Specific services or device requests: _____

_____

_____

Long and short term goals: ______________________________

____

____

____

____

This plan differs from previous treatment because. . . ______________________________

____

____

Expected outcomes: ______________________________

____

____

How will this supplemental treatment augment current treatment? ______________________________

____

____

ENCLOSURES REQUIRED:

1. Medical clearance or referral for services (if old CCS case). 2. Audiological report to support request. 3. Speech and language reports to support request. 4. Previous treatment progress reports. 5. Audiogram. 6. Other useful information for EPSDT review. 7. Any other data to support your request.

(Name) ______________________________

(Facility) ______________________________ ______________________________

(Requested By and Facility Name) (Medi-Cal Provider Number to be authorized)

• •

FOR OFFICIAL? USE:

DATE RECEIVED:	**DATE REVIEWED:**
ADDITIONAL INFO NEEDED:	
RESPONSE DATE: ______________	**BY:** ______________ EPSDT REVIEWER

PRE-COCHLEAR IMPLANT QUESTIONNAIFE FOR REFERRAL SOURCE

CHILD'S NAME:_____

Diagnosis of bilateral deafness, established by audiologic and medical evaluation:

Enclose current reports of audiological evaluation, current audiogram, the make and model of hearing aid(s), electro-acoustic hearing aid data, and hearing aid performance (unaided vs. aided) thresholds.

ANSWER (YES/NO) to the following:

_____ **Is** hearing loss greater than 90-95 dB HTL in the better ear?
_____ Are aided better ear hearing thresholds above 1000 Hz poorer than 50 dB HTL?
_____ Are hearing aids used consistently? All waking hours?
_____ Is speech discrimination for simple sentences and words less than 30%?

Cognitive **ability to use auditory cues:**

_____ Does the child cooperate during clinic visits?
_____ Does child comprehend speech/signing used during your interaction?
_____ Does child understand and respond to commands:?
_____ Does child-use situational cuing for understanding?
_____ ***Is*** child aware of ***speech as*** communication medium?
_____ Does child include expression (facial or body language) in communication?
_____ Does child use voice without signs for communication?
_____ Does child attempt to use oral communication?
_____ Does play interactively with other children and/or family members?
_____ Is child considered Immature, dependent on others to initiate action?
_____ Do parents comply with clinical recommendations for carry over in the home to obtain maximum use of amplification and for **keeping** appointments?
_____ Are parents aware that there is an external device worn with cochlear implant unit?
_____ Are parents informed of all options available to deaf children?

Comment:

Provider's assessment of: Motivation **of candidate and/or commitment of family/care giver(s) to undergo a program of prosthetic fitting and long-term rehabilitation.**

_____

_____

_____

Provider's assessment of **Realistic expectations of the candidate and/or family/ caregiver(s) for post implant educational/vocational rehabilitation as appropriate.**

_____

_____

_____

_____

_____

Provider's assessment of the child's educational program: _____

_____

_____

_____

Provider's assessment of the chiid's individual aural (re)habilitation program: _____

_____

_____

_____

Additional Comments:

Name, address and telephone number of child's educational program:

Teacher's Name:

Name of private setting and clinician and telephone number (if appropriate):-

Revised 5/6/97 rjo

Early, Periodic Screening, Diagnosis and Treatment Supplemental Services

PROVIDER REQUEST FOR MEDICAL FOODS (as defined on the back)

Provider: Please complete the following information and attach ***readable*** copies of current history and physical, progress notes, laboratory reports, anthropometric data/growth grids, or any other information that **supports** the request. Omission of information may result in a deferral or denial of the request.

DATE OF YOUR **REQUEST:** / /

PROVIDER OF MEDICAL NUTRITION THERAPY: Registered Dietitian Address Phone Medi-Cal Provider Number (ii billed through the RD)	PRESCRIBED BY: Health Care Provider Address Phone Medi-Cal Provider Number (if billed to outpatient clinic)

PATIENT INFORMATION

Patient Name	Date of Birth	County of Residence
Medi-Cal Number (or Social Security Number)	CCS Number	

SERVICE REQUEST AND JUSTIFICATION (*attach additional pages as needed*)

☐ A written prescription **signed** by a CCS paneled physician for the specific Medical Foods is attached.

☐ A copy of the nutritional assessment and treatrnent'plan done by a CCS paneled registered dietitian (RD) is attached.

☐ Attach **either** a CCS Request for Service form, or a Treatment Authorization Request (TAR) if you are a **Medi-Cal** provider requesting **fee-for-service.**

Principle Diagnosis	Significant Associated Diagnosis	Date of Onset, Etiology if known

Prognosis

Clinical significance or **functional impairment(s)**

Significant **Medical History** (*remember to attach appropriate medical records to support your request. Describe what services am being provided by the physician*)

Medical justification for specific dietary management of a diise or condition for which specific nutritional requirements exist (guidelines on the back):

☐ Provide documentation that includes: ✔ type of medical food(s), ✔ cost of each medical food, ✔ total amount of each medical food to be provided for the specific period to be covered by this authorization, ✔ name of the **pharmacy** which will dispense the medical food, and ✔ percentage of medical food products which are snack foods (≤ **10%** of the total cost limit)

Submit to the local CCS program or Medi-Cal field office.
If you have questions about using this form, please call the local CCS program or Medi-Cal field office.

Early, Periodic Screening, Diagnosis and Treatment Supplemental Services

INFORMATION ABOUT REQUESTING MEDICAL FOODS

Medical foods are *replacement* food products which **are:**

- ✔ Specially formulated to be consumed or administered enterally;
- ✔ Intended for the specific dietary management of a disease or **condition** for which specific nutritional requirements exist:
- ✔ Prescribed as medically necessary by a California Children's Services paneled physician;
- ✔ Purchasable only through a pharmacy;
- ✔ Required in ***place*** of food products used by the general population;
- ✔ Are safe for the individual **EPSDT-eligible** beneficiary **and** are not experimental;
- ✔ Generally accepted by the professional medical community as effective and proven treatments for the condition for which they are proposed to be used **(scientific** evidence published in peer-review journals).

When justifying the medical necessity for specific dietary management of a disease or condition for which specific nutritional requirements exist, include in your statement:

- ✔ The necessity for the medical foods to treat or ameliorate the beneficiary's medical condition;
- ✔ The reason food products used by the general population cannot be used for the medical condition;
- ✔ Documentation that the food products are specially formulated for the **specific** dietary management of a disease or condition for which specific nutritional requirement exist;
- ✔ Documentation that they are not **requested** solely for the convenience of the beneficiary, family, physician, or other provider of services.
- ✔ Documentation that the medical food products are the most cost-effective, medically accepted mode of treatment available and that they improve the overall health **outcome** as much as, or more than, the established alternatives.

Here is a sample **list for medical food products for a child with phenylketonuria (PKU):**

Medical Food Product	Product Code	Package Amt	Unit Cost	# of Units for 6 mo	TOTAL COS
dp Baking Mix	DPBM0604	4 lb bag	$ 15.00	4	560.00
Low prc cookies .	xxxxxxxx	16 oz box	$5.00	1	$5.00 .
. Snack foods are 7% of the Total Cost (≤ 10 %)				TOTAL COST	$65.00

Early, Periodic Screening, Diagnosis and Treatment Supplemental Services

PROVIDER REQUEST FOR MEDICAL NUTRITION ASSESSMENT

Provider: Please complete the following information and attach readable copies of current history and physical, progress notes, laboratory reports, anthropometric data/growth grids, or any other information that supports the request. Omission of information may result in a deferral or denial of the request.

DATE OF YOUR REQUEST: / /

PROVIDER OF SERVICES: Registered Dietitian Address Phone Medi-Cal Provider Number (if billed through the RD)	PRESCRIBED BY: Health Care Provider Address Phone Medi-Cal Provider Number (ii billed to outpatient clinic)

PATIENT INFORMATION

Patient Name	Date of Birth	County of Residence
Medi-Cal Number (or Social Security Number)	CCS Number	

SERVICE REQUEST AND JUSTIFICATION (*attach additional pages as needed*)

☐ A written, signed request by the patient's physician for medical nutrition assessment is attached.

☐ Attach either a CCS Request for Service form, or a Treatment Authorization Request (TAR) if you are a Medi-Cal provider requesting fee-for-service.

ciple Diagnosis	Significant Associated Diagnosis	Date of Onset, Etiology if known

Prognosis

Clinical significance or functional impairment(s)

Significant Medical History *(remember to attach appropriate medical records to support your request. Describe what services are being provided by the physician.)*

Medical Justification for Providing Nutrition Assessment

Anticipated Frequency and Duration of the Nutrition Assessment (e.g. number of visits and amount of time per visit). (¼ hour = 1 unit)

TOTAL UNITS

When complete, submit your request to the local CCS program or Medi-Cal field office.
If you have questions about using this form, please call the local CCS program of Medi-Cal field office.

Early, Periodic Screening, Diagnosis and Treatment Supplemental Services

PROVIDER REQUEST FOR MEDICAL NUTRITION THERAPY

Provider: Please complete the following information and attach *readable* copies of current history and physical, progress notes, **laboratory reports, anthropometric data/growth** grids, or **any** other information that supports the request. Omission of **information may** result **in a deferral or denial of the request.**

DATE OF YOUR REQUEST: I /

PROVIDER OF SERVICES: *Registered Dietitian* Address Phone **Medi-Cal** Provider **Number** (ii billed through the RD)	**PRECRIBED** BY: **Health** Car.9 Provider Address Phone **Medi-Cal** Provider Number (if billed to **outpatient clinic)**

PATIENT INFORMATION

Patient Name	**Date of Birth**	**County of Residence**
Medi-Cal Number (or Social Security Number)	**CCS** Number	

SERVICE REQUEST AND JUSTIFICATION *(attach additional pages as needed)*

- ☐ A written, signed prescription by the physician for medical nutrition therapy is attached.
- ☐ Attach either a CCS Request for Service form, or a Treatment Authorization Request (TAR) if you are a Medi-Cal provider requesting **fee-for-service.**
- ☐ A copy of the nutritional assessment done by a registered dietitian **(RD)** is attached.
- ☐ A **nutritional** plan of treatment, including therapeutic goals and anticipated time for achievement, is attached.
- ☐ Parenfflegal guardian and/or patient agree(s) to cooperate **with** the proposed medical nutrition therapy.

Principle Diagnosis	**Significant Associated Diagnosis**	**Date of Onset, Etiology if known**

Prognosis

Clinical significance or **functional impairment(s)**

Significant Medical History *(remember to attach appropriate medical records to support your request. Describe what services are being provided by the physician.)*

Mediil Justification for Providing **Medical Nutrition Therapy**

nticipated Frequency end **Duration** of the **Medical Nutrition** Therapy for **a** Period of **(6)** Six Months:

(¼ hour = 1 unit)
Total Units _____

Submit to the local CCS **prog**.... ... **...edi-Cal** field office.
If you have questions about using this form, please call the local CCS program or Medi-Cal field **office.**

STATE OF CALIFORNIA-HEALTH AND WELFARE AGENCY PETE WILSON, Governo

DEPARTMENT OF HEALTH SERVICES

714/744 P STREET
P. O. Box 942732
SACRAMENTO. CALIFORNIA 94234-7320
(916) 654-0521

Initial Request ?
Renewal ● 7

Date: _____

OXIMETER INFORMATION

Patient Name: _____ DOB.: _____ Age: _____

TO BE **COMPLETED** BY M.D.

Diagnosis (List **all pertinent,** be **specific):** _____

_____

Hospital admissions past year - give *dates, hospital, diagnosis*: _____

_____

O_2 requirement - %, flow, **duration,** etc.: _____

_____

Give recent **oximeter** readings. include **range, average, and** dates. **Describe** fluctuation(s): _____

_____

_____

List other monitors or **alarms** to be used. Explain why these **are** not **sufficient:** _____

_____

Explain what intervention **caregiver** will **provide** based on **oximeter** readings. _____

_____

_____

Estimate length of **need** for **oximeter:** _____

Physician's *Signature* _____ **Print Name & License** _____

Date of Physicians signature _____

Attach MD's recent outpatient evaluations and notes, or a narrated summary. Also, **attach a copy of H. & P. and discharge summary of most recent hospitalization, or a progress summary if** currently an **inpatient. These RECORDS** ARE **MANDATORY for consideration of** request.

DME PROVIDER

Model requested: _____ Brand: _____

Monthly rental: $_____ Provider's actual invoice purchase cost: S _____

List the least **expensive model** available on the market: _____

Cost of **rental** or purchase of this model: _____

Explain why this model is **not** adequate for this child: _____

*EPSDTSS PULSE **OXIMETER** REQUEST CHECK LIST*

- ❑ EPSDT SS Worksheet
- ❑ Pulse Oximeter form filled out (preferably by a Pulmonologist).
- ❑ Signed physician's prescription for pulse oximeter.
- ❑ History and physical or current discharge summary. Include full center report that specifically justifies the request for a **pulse** oximeter.
- ❑ Documentation of significant respiratory or cardiopuhnonary disease requiring continuous in-home monitoring (include **frequency and readings)(basically instability).**
- ❑ Documentation of variable oxygen needs - requiring immediate changes by caregiver.
- ❑ **Oxygen** settings and duration.
- ❑ Is child on a ventilator in the home? If yes, how many hours per day.____
- ❑ Current 02 saturations if machine already in the home.
- ❑ What other related equipment in the home, i.e., Apnea monitor.
- ❑ Explanation of why just monitoring signs and symptoms is not enough.
- ❑ Explanation why periodic outpatient monitoring would not be effective.
- ❑ Explanation of what interventions the caregiver will provide based on oximeter readings.
- ❑ Rental vs. purchase.
- ❑ Anticipated length of need.
- ❑ Documentation that parent has been trained in the use of, and interpretation of reading from the pulse oximeter.
- ❑ Is the child receiving licensed nursing services in the home? If so how many hours per day? Waiver or EPSDT Supplemental Nursing Services?

EPSDT Supplemental Services Occupational Therapy Request Documentation Checklist

The purpose of the EPSDT Supplemental Services Request Documentation Checklist is to assist county CCS programs and State CCS Regional Offices in assembling legible information required for processing of an EPSDT Supplemental Services request by the designated EPSDT Supplemental Services subcommittee. Use of the checklist may prevent either delays in processing caused by the subcommittee's deferral of a request for more information or denial. Omission of applicable information on the checklist may also cause the request to be deferred or denied.

___ Genera!

- 0 OT services requested exceed 2x per month
- 0 Patient is not receiving OT through the Medical Therapy Program

___ Current Physician's Prescription

- 0 Specific for service to be provided (by discipline)
- 0 Frequency and duration of prescription identified

___ Current Physician's Report

- 0 Physical findings
- 0 Addresses need for therapy intervention
- 0 Identifies condition that therapy will correct or ameliorate
- 0 Treatment plan identifies functional goal(s) for therapy intervention

___ Current Occupational Therapy Report

- 0 Physical findings
- 0 Summary of functional deficits to be addressed by therapy
- 0 Patient's functional status in each area of deficit to be addressed
- 0 Treatment plan includes functional goals to address deficits targeted by therapy assessment, and anticipated time required to achieve these goals
- 0 Patient/Caregiver input into the treatment plan
- 0 Functional outcomes/benefits of any previous therapy services

FOR CCS USE ONLY (4/3/96)

EPSDT Supplemental Scrviccs Durable Medical Equipment Rcqucst Documentation Checklist

The purpose of the EPSDT Supplemental Services Request Documentation Checklist is to assist county CCS programs and State CCS Regional Offices in assembling legible information required for processing of an EPSDT Supplemental Services request by the designated EPSDT Supplemental Services subcommittee. Use of the checklist may prevent either delays in processing caused by the subcommittee's deferral of a request for more information or denial. Omission of applicable information on the checklist may also cause the request to be deferred or denied.

General

- o DME item is not a benefit of the regular Medi-Cal program
- o DME item is a benefit of the CCS program or treats CCS eligible condition
- o Provider information (provider name, nddress, phone number, and Medi-Cal provider status/number)
- o Catalog listing, prices, description/photo of item(s)

Current Physician's Prescription

- o Specific for DME item
- o Identifies significant modifications/additions to basic item

Current Physician's Report

- o Physical findings
- o Addresses needs for specific DME item

Current Physical Therapy/Occupational Therapy Report

- o Physical findings
- o Functional status related to DME item requested
- o Home/School/Community Accessibility Assessment (ii applicable)

The following items must be addressed in either the MD's or PT/OT report:

Justification (initial item)

- o Medical necessity of basic DME item
- o Each addition/modification/accessory to basic DME item

Justification (new/replacement/upgrade)

- o Why current item no longer meets patient needs
- o Functional opportunities new item/upgrade provides
- o Medical necessity of basic DME item
- o Each addition/modification/accessory to basic DME item

Comparisons (if applicable)

- o What other similar DME items were considered?
- o Why this particular DME item was chosen over others considered.
- o Is this the most cost effective method of meeting patient needs?

Trial Period (if applicable)

Follow-Up Training (if applicable)

Meets all requirements of CCS DME Guidelines

FOR CCS USE ONLY (4/3/96)

CALIFORNIA CHILDREN SERVICES/EPSDT MENTAL HEALTH SERVICES REQUEST
DATE OF INITIAL REQUEST: / /9 DATE OF ADDED REQUEST / /9

I. CLIENT IDENTIFICATION:

CLIENT NAME		DATE OF BIRTH	
MED-CAL NUMBER (14 digits)		COUNTY/CCS#	

II. PROVIDER INFORMATION

PROVIDER NAME		EPSDT #/MC#	
PHONE NUMBER		LICENSE TYPE	
ADDRESS		LICENSE #	
CITY		ZIP	

III. SERVICE REQUEST AND JUSTIFICATION (ATTACH ADDITIONAL SHEETS IF NEEDED)

INDICATE NUMBER OF SESSIONS REQUESTED: (INDICATE GOALS FOR EACH TYPE OF SERVICE REQUESTED IN SECTION IX)	-INDIVIDUAL ___ FAMILY ___ GROUP Other: _____ TIRE NEEDED TO COMPLETE ABOVE SESSIONS= - WEEKS	IF FAMILY THERAPY REQUESTED, INDICATE NAMES AND RELATIONSHIPS OF PERSONS TO BE INCLUDED	Family therapy will include : ___ ___ ___ ___
HOW WAS CHILD REFERRED AND WHY (INCLUDE AS MUCH AS IS KNOWN ABOUT PRESENTING PROBLEM-FREQUENCY CIRCUMSTANCES, ETC.)			
OTHER AGENCIES INVOLVED WITH CLIENT/FAMILY			
YOUR EXPERIENCE PROVIDING SERVICE REQUESTED TO PERSONS THE AGE OF THE CLIENT			

IV. FUNCTIONAL IMPAIRMENTS

[I HOME	
[ ] SCHOOL/WORK	
[ ] SOCIAL	
[ ] COMMUNITY	
[ ] MEDICAL/OTHER	

Attach psychosocial reports if any available.
YOU may stop here if no more than 3 evaluation sessions are requested

VI. PREVIOUS. **TREATMENT** FOR **PROBLEM & OUTCOME(S):**

FROM	To	SERVICES PROVIDED/PROVIDED BY	RESULTS OF SERVICES

VII. SIGNIFICANT FAMILY HISTORY/FAMILY FUNCTIONING

VIII. DSM DIAGNOSIS: (Give code & describe symptoms that justify diagnoses)

AXIS I CLINICAL			
AXIS 2:PERSONALITY			
AXIS 3: MEDICAL			
AXIS 4: PSYCHOSOCIAL AND ENVIRONMENTAL PROBLEMS			
AXIS 5: GLOBAL ADAPTIVE FUNCTIONING-BEST		CURRENT GAF	

IX. TREATMENT PLAN/GOALS: NAME OF CLIENT_____ Pg 3

GOALS FOR INDIVIDUAL THERAPY

GOALS FOR(CHECK ONE): GROUP[ ] FAMILY THERAPY1]

TIMELINE	BASELINE/CURRENT STATUS	SHORT TERM GOALS/OBJECTIVES: If family therapy is requested some goals should be for changes in family functioning)
IN_____ MONTHS		
IN_____ MONTHS		
IN_____ MONTHS		
IN____ MONTHS		
IN_____ MONTHS		
IN_____ MONTHS		

TREATMENT METHODS/EXPLANATION OF TREATMENT PLAN:

'I CERTIFY THAT THE CLIENT'S PARENT(S) OR CLIENT, IF OVER 18 AGREES TO THE TREATMENT PLAN:

_____
SIGNATURE OF THERAPIST

{EPSDTREQ.REV}

Date:__/____/9__ Name of Client _____ Pg.4

TO REQUEST EXTENSIONS OF PREVIOUS AUTHORIZATIONS FOR TREATMENT

Please send copies of pages l-3 with this page to extend previously authorized treatment

PROGRESS MADE DURING PREVIOUS TREATMENT:

REASONS FURTHER TREATMENT IS NEEDED:

CHANGES IN GOALS/OBJECTIVES

NEW TARGET' DATE	CURRENT BASELINE	NEWOBJECTIVE

EPSDT SUPPLEMENTAL SERVICES MENTAL HEALTH SERVICES REQUEST DATE OF REQUEST:5/7/96

I. CLIENT IDENTIFICATION:

CLIENT NAME	SMITH, Nancy	DATE OF BIRTH	7-15-84
MED- CAL NUMBER	59-90-9666666-6-66	COUNTY CCS/NA	55555555

II. PROVIDER INFORMATION

PROVIDER NAME	Ima Goodworker, LCSW	AGENCY	
PHONE NUMBER	(777)777-7777	LICENSE TYPE	LCSW
ADDRESS	P.O.Box 66666	LICENSE NUMBER	LCS 00000
CITY	Anytown	CALIFORNIA ZIP	95888

III. SERVICE. REQUEST AND JUSTIFICATION(ATTACH ADDITIONAL SHEETS IF NEEDED)

INDICATE NUMBER OF SESSIONS REQUESTED: (INDICATE GOALS FOR EACH TYPE OF SERVICE REQUESTED IN SECTION IX)	4 INDIVIDUAL 4 FAMILY __ GROUP __ Other: TIME NEEDED TO COMPLETE ABOVE SESSIONS=8-10WEEKS	IF FAMILY THERAPY REQUESTED, INDICATENAMES AND RELATIONSHIPS OF INDIVIDUALS TO BE INCLUDED	Family therapy will include Nancy and her mother CONTINUED ON ATTACHED SHEET: Yes No x
HOW WAS CHILD REFERRED AND WHY (INCLUDE AS MUCH AS IS KNOWN ABOUT PRESENTING PROBLEM-FREQUENCY CIRCUMSTANCES, ETC.)	This is an almost 12 year old child with diabetes requiring insulin injections and asthma. The request is for an eight session extension of treatment. Nancy's mother's work schedule had changed which reduced mother's availability to the child just as treatment was ending, and Nancy regressed. She had a depressive episode which included increased lethargy, she quit doing homework, and she stopped drawing and preparing her injections.		
OTHER AGENCIES INVOLVED WITH CLIENT/FAMILY	U. C. Medical Center-Jane Do, MD		
YOUR EXPERIENCE PROVIDING THE TYPE OF SERVICE REQUESTED TO PERSONS THE AGE OF THE CLIENT	Many years experience working with children and certified by Play Therapy Assn.		

ATTACH ANY RELEVANT MEDICAL OR PSYCHOSOCIAL HISTORY (ATTACHED:Yes No X)

'YOU CAN STOP HERE IF TEE REQUEST IS FOR AUTHORIZATION OF NO MORE THAN THREE EVALUATION SESSIONS

IV. DSM DIAGNOSIS: Give code and descriptions with date of onset, if known

AXIS I CLINICAL	309.0 Adjustment disorder with depressed mood		
AXIS 2:PERSONALITY	No DX		
AXIS 3: MEDICAL	Insulin dependent Diabetes and Asthma		
AXIS 4: PSYCHOSOCTAL AND ENVIRONMENTAL PROBLEMS(Describe)	Change in single, working mother's hours, social isolation, with no supports for mom or Nancy		
AXIS 5: GLOBAL ADAPTIVE FUNCTIONING- BEST	70	CURRENT GAF	60
			CONTINUED ON REVERSE

V. HISTORY OF PROBLEM

Nancy talked of suicide at the beginning of treatment and no longer does so. She began to comply with her medical regimen, became less lethargic and began to take interest in her studies and friends at school. Her grades improved from failing to passing Nancy experienced increased asthma symptoms and medical compliance problems but has improved in both. She lives in a very bad neighborhood and her mother has been overwhelmed, finding it easier to give Nancy shots than teach Nancy to draw and give her own.

VI. PREVIOUS TREATMENT FOR PROBLEM & OUTCOME(S)

FROM	TO	SERVICES PROVIDED	RESULTS OF SERVICES
3/1/96	Present	13 sessions to be completed June 1996	Improving but setback see sections III and V, above.

VII. SIGNIFICANT FAMILY HISTORY

Poverty, single mother with history of being the victim of abuse. She is distrustful and very isolated. The mother is overwhelmed and has no supports for herself. The neighborhood is dangerous but the mother refuses to consider moving if she cannot have a house or duplex/halfplex, and is probably too overwhelmed to contemplate the added stress of moving, in any event.

VIII. FUNCTIONAL IMPAIRMENT-PROGRESS TO -DATE

[x] HOME	Improved, with less defiance of medical regimen. Her allergies are well controlled for the first time, but she is still not fully compliant with her diabetes Tx. She is afraid of her shots and resists even drawing the insulin from the bottle-lethargic at home.
[X] SCHOOL/WORK	Grades improved from failing and she shows improved interaction with other children.
[X] SOCIAL	Isolated family in a bad neighborhood, with few friends at home.
[X] COMMUNITY	Mother trusts few people and maintains isolation.
[x] OTHER	Nancy's diabetes is a real challenge in this family that would be struggling without this medical problem. She has begun to draw her own shots intermittently.

IX. GOALS PLEASE STATE GOALS FOR EACH TYPE OF SERVICE REQUESTED, IN MEASURABLE OR OBSERVABLE TERMS THAT WILL ALLOW EVALUATION OF THE EFFICACY OF THE TREATMENT: EG: REDUCING ANXIETY ABOUT SCHOOL ATTENDANCE CAN BE STATED AS "MISSING SCHOOL WILL BE REDUCED FROM ONE UNEXCUSED ABSENCE PER WEEK TO 'LESS THAN ONE PER MONTH" WHAT THE CLIENT WILL VERBALIZE THAT INDICATES PROGRESS. USE ADDITIONAL PAGES IF NEEDED.

LONG TERM GOAL(S):1. Individ:Maintain school performance gains. 2. Family:Mother will be supported to use her authority as a patent, and encouraged to teach Nancy and insist that Nancy draw and give her own insulin shots.

3.Both: Decrease depression. 4. Increase Nancy's expression of her needs and wants verbally. 5. Increase Nancy's self esteem and support Nancy's feelings of self efficacy concerning self care, peers, and school.

TARGET DATE	SHORT TERM GOALS/OBJECTIVES
Summer 96	Nancy will give her own shots two days per week, on the days when mother is home from work. She will attend camp for children with Diabetes, in August 1996.
June 96	Nancy will prepare all shots. Nancy will state one need/wish verbally each day. Nancy will converse with one peer each day.

I CERTIFY THAT THE CLIENT'S PARENT(S) OR CLIENT, IF OVER 18 AGREES TO THE TREATMENT PLAN: SIGNATURE OF THERAPIST

DEPARTMENT OF HEALTH SERVICES
7141744 P STREET
P. 0. Box 942732
SACRAMENTO, CALIFORNIA 94234-7320
(916) 657-I 604

Children's Medical Services
California Children's Services Program

_____

_____

_____

TAR#: _____

RE: _____ Medi-Cal#: _____

DOB: _____

Dear Children's Medical Services Representative:

The enclosed request was received by the Medi-Cal Operations Division, Early & Periodic Screening, Diagnosis and Treatment (EPSDT) Unit aud appears to be a Children's Medical Services (CMS), California Children's Services (CCS) eligible condition. The provider has been asked to forward the request to you. We appreciate your review of the request and return of this form indicating the action taken:

- ☐ Case Mauagement will be provided by CCS.
- ☐ Diagnosis is not a CCS eligible condition and we are returning the Treatment Authorization Request (TAR).
- ☐ Services requested will not treat a CCS eligible condition and we are returning the TAR.
- ☐ Services requested are not documented to be medically necessary and we are returning the TAR.
- ☐ Provider is not a CCS panel provider.
- ☐ Other: _____

_____
Signature of CCS Repmentative

_____
Date

Please return thii form to:

Departmeut of Health Services
Medi-Cal Field Office

_____

_____

Thank you for your cooperation.
Enclosure

DEPARTMENT OF HEALTH SERVICES
7 141744 P STREET
P. 0. Box 942732
SACRAMENTO, CALIFORNIA 94234-7320
(916) 657-1604

RE: _____

Medi-Cal #. _____

Dear _____

The enclosed Treatment Authorization Request (TAR) # _____ was received by _____ on _____ for the beneficiary named above. The Medi-Cal Program is required to refer to the California Children's Service (CCS) program, any beneficiary under age 21 who has a medical or surgical condition which would qualify for services through CCS according to title 22 California Code of Regulations section 51013. Please submit your request for _____ services to the address indicated below.

Children's Medical Services (CMS)
California Children's Services Program

_____

_____

In order to expedite review, do not send a TAR, instead, your request should contain copies of the TAR and this letter, as well as any supporting documentation.

Thank you for your cooperation. If you have any additional questions, please contact the CMS county representative identified above at ( ) _____

Smcerely ,

_____

_____

Enclosure

cc: Children's Medical Services (CMS)
California Children's Services (CCS) Program

_____

_____